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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

BTG INTERNATIONAL LIMITED, JANSSEN BIOTECH, INC., JANSSEN ONCOLOGY, INC., JANSSEN RESEARCH & DEVELOPMENT, LLC, Plaintiffs, v. ACTAVIS LABORATORIES FL, INC., AMNEAL PHARMACEUTICALS LLC, AMNEAL PHARMACEUTICALS OF NEW YORK, LLC, APOTEX CORP., APOTEX INC., CITRON PHARMA LLC, DR. REDDY'S LABORATORIES, INC., DR. REDDY'S LABORATORIES, LTD., MYLAN PHARMACEUTICALS INC., MYLAN, INC., PAR PHARMACEUTICAL, INC., PAR PHARMACEUTICAL COMPANIES, INC., SUN PHARMACEUTICALS INDUSTRIES, LTD., SUN PHARMACEUTICALS INDUSTRIES, INC., TEVA PHARMACEUTICALS USA, INC., WEST-WARD PHARMACEUTICAL CORP., HIKMA PHARMACEUTICALS, LLC, WOCKHARDT BIO AG, WOCKHARDT USA LLC, WOCKHARDT LTD., HETERO USA INC., HETERO LABS LIMITED UNIT-V, and HETERO LABS LIMITED, Defendants.	)	Civil Action No.: 2:15-cv-05909-KM-JBC

FIRST AMENDED COMPLAINT FOR PATENT INFRINGEMENT[1]

Plaintiffs BTG International Limited ("BTG"), Janssen Biotech, Inc. ("Janssen Biotech"), Janssen Oncology, Inc. ("Janssen Oncology"), and Janssen Research & Development, LLC ("Janssen R&D"),[2] hereby amend their Complaint against Defendants Actavis Laboratories FL, Inc. ("Actavis Labs. FL"), Actavis Pharma, Inc. ("Actavis Pharma"), Actavis, Inc.,[3] Amneal Pharmaceuticals LLC ("Amneal Pharms. LLC"), Amneal Pharmaceuticals of New York, LLC ("Amneal Pharms. NY),[4] Apotex Corp., Apotex Inc.,[5] Citron Pharma LLC ("Citron Pharma"), Dr. Reddy's Laboratories, Inc. ("DRL Inc."), Dr. Reddy's Laboratories, Ltd. ("DRL Ltd."),[6] Mylan Pharmaceuticals Inc. ("Mylan Pharms."), and Mylan, Inc.,[7] Par Pharmaceutical, Inc. ("Par

[1] Defendants, through their respective counsel, consented to the filing of this Amended Complaint, as follows: Apotex Corp. and Apotex Inc., by email dated September 21, 2015; Teva Pharmaceuticals USA, Inc., by email dated September 22, 2015; Actavis Laboratories FL, Inc., Actavis Pharma, Inc., Actavis, Inc., Amneal Pharmaceuticals LLC, Amneal Pharmaceuticals of New York, LLC, Dr. Reddy's Laboratories, Inc., Dr. Reddy's Laboratories, Ltd., Sun Pharmaceuticals Industries, Ltd., Sun Pahramceuticals Industries, Inc., Westward Pharmaceutical Corp., The Arab Pharmaceutical Manufacturing Co., Hikma Pharmaceuticals, PLC, and Hikma Pharmaceuticals, LLC, by email dated September 24, 2015; and Wockhardt Bio AG, Wockhardt USA LLC, and Wockhardt Ltd., by email dated September 25, 2015. *See* Fed. R. Civ. P. 15(a)(2).

[2] Janssen Biotech, Janssen Oncology, and Janssen R & D hereinafter are collectively referred to as "Janssen." BTG and Janssen hereinafter are referred to collectively as "Plaintiffs."

[3] Actavis Labs. FL, Actavis Pharma, and Actavis, Inc. hereinafter are collectively referred to as "Actavis." Pursuant to the September 24, 2015 Stipulation and Order Regarding Jurisdiction and Dismissing Defendants Actavis, Inc. and Actavis Pharma, Inc., Without Prejudice (D.I. No. 46), which applies and remains in effect, Actavis, Inc. and Actavis Pharma, Inc. were removed as named defendants in this action.

[4] Amneal Pharms. LLC and Amneal Pharms. NY hereinafter are collectively referred to as "Amneal."

[5] Apotex Corp. and Apotex Inc. are hereinafter collectively referred to as "Apotex."

[6] DRL Inc. and DRL Ltd. are hereinafter collectively referred to as "DRL."

[7] Mylan Pharms. and Mylan Inc. hereinafter are collectively referred to as "Mylan."

Pharm. Inc."), Par Pharmaceutical Companies, Inc. ("Par Pharm. Cos. Inc."),[8] Sun Pharmaceuticals Industries, Ltd. ("Sun Ltd."), Sun Pharmaceuticals Industries, Inc. ("Sun Inc."),[9] Teva Pharmaceuticals USA, Inc. ("Teva Pharms. USA"), Teva Pharmaceuticals Industries, Ltd. ("Teva Pharms. Indus. Ltd."),[10] West-Ward Pharmaceutical Corp. ("West-Ward Pharm."), The Arab Pharmaceuticals Manufacturing Co. ("Arab Pharm. Manuf. Co."), Hikma Pharmaceuticals, PLC ("Hikma Pharms. PLC"), Hikma Pharmaceuticals, LLC ("Hikma Pharms. LLC"),[11] Wockhardt Bio AG ("Wockhardt Bio"), Wockhardt USA LLC ("Wockhardt USA"), Wockhardt Ltd.,[12] Hetero USA Inc. ("Hetero USA"), Hetero Labs Limited Unit-V ("Hetero Unit-V"), and Hetero Labs Limited ("Hetero Ltd."),[13] to the best of their knowledge, information and belief, hereby allege as follows:

NATURE OF THE ACTION

1. This is a civil action for patent infringement arising under the patent laws of the United States, Title 35, United States Code, in response to the submission of Abbreviated New

[8] Par Pharm. Inc. and Par Pharm. Cos. Inc. hereinafter are collectively referred to as "Par."

[9] Sun Ltd. and Sun Inc. hereinafter are collectively referred to as "Sun."

[10]Teva Pharms. USA and Teva Ltd. hereinafter are collectively referred to as "Teva." Pursuant to the September 3, 2015 Stipulation and Order Consenting to Jurisdiction and Dismissing Defendant Teva Pharmaceutical Industries Ltd., Without Prejudice (D.I. No. 41), which applies and remains in effect, Teva Ltd. was removed as a named defendant in this action.

[11]West-Ward Pharm., Arab Pharm. Manuf. Co., Hikma Pharms. PLC, and Hikma Pharms. LLC hereinafter are collectively referred to as "Hikma/West-Ward." Pursuant to the September 15, 2015 Stipulation and Order Consenting to Jurisdiction and Dismissing Defendants The Arab Pharmaceutical Manufacturing Co. and Hikma Pharmaceuticals, PLC, Without Prejudice (D.I. No. 44), which applies and remains in effect, Arab Pharm. Manuf. Co. and Hikma Pharms. PLC were removed as named defendants in this action.

[12]Wockhardt Bio, Wockhardt USA, and Wockhardt Ltd. hereinafter are collectively referred to as "Wockhardt."

[13] Hetero USA, Hetero Unit-V, and Hetero Ltd. hereinafter are collectively referred to as "Hetero."

Drug Applications ("ANDAs") by Defendants Actavis, Amneal, Apotex, Citron Pharma, DRL, Mylan, Par, Sun, Teva, Hikma/West-Ward, and Wockhardt to the United States Food and Drug Administration (the "FDA") seeking approval to market a generic version of Janssen's ZYTIGA® (abiraterone acetate) Tablets ("ZYTIGA® (abiraterone acetate)") drug product prior to the expiration of United States Patent No. 5,604,213 ("the '213 patent"), and United States Patent No. 8,822,438 ("the '438 patent").

THE PARTIES

2. Plaintiff BTG is a company organized and existing under the laws of the United Kingdom, with its principal place of business at 5 Fleet Place, London, EC4M 7RD United Kingdom.

3. Plaintiff Janssen Biotech is a corporation organized and existing under the laws of Pennsylvania, with its principal place of business at 800/850 Ridgeview Drive, Horsham, PA 19044.

4. Plaintiff Janssen Oncology is a corporation organized and existing under the laws of Delaware, with its principal place of business at 10990 Wilshire Blvd., Los Angeles, CA 90024.

5. Plaintiff Janssen R&D is a limited liability company organized and existing under the laws of New Jersey, with its principal place of business at 920 Route 202 South, Raritan, NJ 08869.

6. Upon information and belief, Defendant Actavis Labs. FL is a corporation organized and existing under the laws of Florida, having a principal places of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, NJ 07054 and 4955 Orange Drive, Davie, FL 33314.

7. Upon information and belief, Defendant Actavis Pharma is a corporation organized and existing under the laws of Delaware, having a principal place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, NJ 07054. Upon information and belief, Actavis Pharma is registered with the State of New Jersey's Division of Revenue and Enterprise Services as a business operating in New Jersey under Business ID No. 0100573928, and has appointed The Corporation Trust Company, 820 Bear Tavern Road, West Trenton, NJ 08628, as its registered agent for service of process in New Jersey.

8. Upon information and belief, Defendant Actavis, Inc. is a corporation organized and existing under the laws of Nevada, having a principal place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, NJ 07054.

9. Upon information and belief, Actavis Labs. FL is a wholly-owned subsidiary of Actavis, Inc.

10. Upon information and belief, Actavis Pharma. is a wholly-owned subsidiary of Actavis, Inc.

11. Upon information and belief, Defendant Amneal Pharms. LLC is a limited liability company organized and existing under the laws of Delaware, having a principal place of business at 400 Crossing Boulevard, Bridgewater, NJ 08807. Upon information and belief, Amneal Pharms. LLC is registered with the State of New Jersey's Division of Revenue and Enterprise Services as a business operating in New Jersey under Business ID No. 0600211542, and has appointed The Corporation Trust Company, 820 Bear Tavern Road, West Trenton, NJ, 08628, as its registered agent for service of process in New Jersey. Upon information and belief, Amneal Pharms. LLC is registered with the State of New Jersey's Department of Health as a drug Manufacturer and Wholesaler, under Registration No. 5002991.

12. Upon information and belief, Defendant Amneal Pharms. NY is a limited liability company organized and existing under the laws of Delaware, having a principal place of business at 85 Adams Avenue, Hauppauge, NY 11788. Upon information and belief, Amneal Pharms. NY is registered with the State of New Jersey's Department of Health as a drug Manufacturer, under Registration No. 5003663.

13. Upon information and belief, Amneal Pharms. NY is a wholly-owned subsidiary of Amneal Pharms. LLC.

14. Upon information and belief, Defendant Apotex Corp. is a corporation organized and existing under the laws of Delaware, having a principal place of business at 2400 North Commerce Parkway, Suite 400, Weston, FL 33326. Upon information and belief, Apotex Corp. is registered with the State of New Jersey as a drug Wholesaler, under Registration No. 5003192.

15. Upon information and belief, Defendant Apotex Inc. is a corporation organized and existing under the laws of Canada, having a principal place of business at 150 Signet Drive, North York, Ontario M9L 1T9, Canada.

16. Upon information and belief, Apotex Corp. is a wholly-owned subsidiary of Apotex Inc.

17. Upon information and belief, Apotex Corp. is the authorized U.S. agent for Apotex Inc.

18. Upon information and belief, Defendant Citron Pharma is a corporation organized and existing under the laws of New Jersey, having principal places of business at 2 Tower Center Boulevard, Suite 1101, East Brunswick, NJ 08816 and at 11 Maacka Dr., Holmdel, NJ 07733. Upon information and belief, Citron Pharma is registered with the State of New Jersey's Division of Revenue and Enterprise Services as a business operating in New Jersey under

Business ID No. 0400540334, and has appointed Vimal Kavuru, 11 Maacka Dr., Holmdel, NJ, 07733, as its registered agent for service of process in New Jersey. Upon information and belief, Citron Pharma is registered with the State of New Jersey's Department of Health as a drug Wholesaler, under Registration No. 5004558.

19. Upon information and belief, Defendant DRL Inc. is a corporation organized and existing under the laws of New Jersey, having a principal place of business at 107 College Road East, Princeton, NJ 08540. Upon information and belief, DRL Inc. is registered with the State of New Jersey's Division of Revenue and Enterprise Services as a business operating in New Jersey under Business Id. No. 0100518911, and has appointed Umang Vohra, 107 College Road East, Princeton, NJ 08540, as its registered agent for service of process in New Jersey. Upon information and belief, DRL Inc. is registered with the State of New Jersey's Department of Health as a drug Manufacturer and Wholesaler, under Registration No. 5002312.

20. Upon information and belief, Defendant DRL Ltd. is a public limited liability company organized and existing under the laws of India, a principal place of business at 8-2-337, Road No. 3, Banjara Hills, Hyderabad, Telangana, India 500 034.

21. Upon information and belief, DRL Inc. is a wholly-owned subsidiary of DRL Ltd.

22. Upon information and belief, DRL Inc. is the authorized U.S. agent for DRL Ltd.

23. Upon information and belief, Defendant Mylan Pharms. is a corporation organized and existing under the laws of West Virginia, having a principal place of business at 871 Chestnut Ridge, Morgantown, West Virginia 26505. Upon information and belief, Mylan Pharms. is registered with the State of New Jersey's Division of Revenue and Enterprise Services as a business operating in New Jersey under Business ID No. 010021477, and has appointed The Corporation Service Company, 830 Bear Tavern Road, West Trenton, NJ, 08628,

as its registered agent for service of process in New Jersey. Upon information and belief, Mylan Pharms. is registered with the State of New Jersey's Department of Health as a drug Manufacturer and Wholesaler, under Registration No. 50037662.

24. Upon information and belief, Defendant Mylan, Inc. is a corporation organized and existing under the laws of Pennsylvania, having a principal place of business at 1000 Mylan Boulevard, Robert J. Coury Global Center, Canonsburg, PA, 15317. Upon information and belief, Mylan Inc. is registered with the State of New Jersey's Division of Revenue and Enterprise Services as a business operating in New Jersey under Business ID No. 0100971292, and has appointed The Corporation Service Company, 830 Bear Tavern Road, West Trenton, NJ, 08628, as its registered agent for service of process in New Jersey.

25. Upon information and belief, Mylan Pharms. is a wholly-owned subsidiary of Mylan Inc.

26. Upon information and belief, Defendant Par Pharm. Inc. is a corporation organized and existing under the laws of Delaware, having principal places of business at One Ram Ridge Road, Chestnut Ridge, NY, 10977 and at 300 Tice Boulevard, Woodcliff Lake, New Jersey 07677 (Corporate Headquarters) and Morris Corporate Center 2, One Upper Pond Road, Building D, Parsippany, NJ 07054 (Sales & Administration). Upon information and belief, Par Pharm. Inc. is registered with the State of New Jersey's Division of Revenue and Enterprise Services as a business operating in New Jersey under Business I.D. No. 0100071541, and has appointed Thomas Haughey, 300 Tice Boulevard, Woodcliff Lakes, NJ 07677, as its registered agent to accept service of process. Upon information and belief, Par Pharm. Inc. is registered with the State of New Jersey's Department of Health as a drug Manufacturer and Wholesaler, under Registration No. 5004032.

27. Upon information and belief, Defendant Par Pharm. Cos. Inc. is a corporation organized and existing under the laws of Delaware, having principal places of business at One Ram Ridge Road, Chestnut Ridge, NY, 10977 and at 300 Tice Boulevard, Woodcliff Lake, New Jersey 07677 (Corporate Headquarters) and Morris Corporate Center 2, One Upper Pond Road, Building D, Parsippany, NJ 07054 (Sales & Administration). Upon information and belief, Par Pharm. Cos. Inc. is registered with the State of New Jersey's Division of Revenue and Enterprise Services as a business operating in New Jersey under Business I.D. No. 0100946477, and has appointed Thomas Haughey, 300 Tice Boulevard, Woodcliff Lakes, NJ 07677, as its registered agent to accept service of process.

28. Upon information and belief, Par Pharm. Inc. is a wholly-owned subsidiary of Par Pharm. Cos. Inc.

29. Upon information and belief, Defendant Sun Inc. is a corporation organized and existing under the laws of Michigan, having a principal place of business at 279 Prospect Plains Rd., Cranbury, NJ 08512. Upon information and belief, Sun Inc. is registered with the State of New Jersey's Division of Revenue and Enterprise Services as a business operating in New Jersey under Business ID No. 0100970132, and has appointed The Corporation Trust Company, 820 Bear Tavern Road, West Trenton, NJ, 08628, as its registered agent for service of process in New Jersey. Upon information and belief, Sun Inc. is registered with the State of New Jersey's Department of Health as a drug Manufacturer and Wholesaler, under Registration No. 5003437.

30. Upon information and belief, Defendant Sun Ltd. is a company organized and existing under the laws of India, having a principal place of business at Acme Plaza, Andheri-Kurla Road, Andheri (East), Mumbai, Maharashtra 400059 India.

31. Upon information and belief, Sun Inc. is a wholly-owned subsidiary of Sun Ltd.

32. Upon information and belief, Sun Inc. is the authorized U.S. agent for Sun Ltd.

33. Upon information and belief, Defendant Teva Pharms. USA is a corporation organized and existing under the laws of Delaware, having a principal place of business at 1090 Horsham Road, North Wales, PA 19454. Upon information and belief, Teva Pharms. USA is registered with the State of New Jersey's Division of Revenue and Enterprise Services as a business operating in New Jersey under Business ID No. 0100250184, and has appointed Corporate Creations Network Inc., 811 Church Road Suite 105, Cherry Hill, NJ, 08002, as its registered agent for service of process in New Jersey. Upon information and belief, Teva Pharms. USA is registered with the State of New Jersey's Department of Health as a drug Manufacturer and Wholesaler, under Registration No. 5000583 and as a drug Wholesaler, under Registration No. 5003436.

34. Upon information and belief, Defendant Teva Pharms. Indus. Ltd. is a company organized and existing under the laws of Israel, having a principal place of business at 5 Basel Street, Petach Tikva 49131 Israel.

35. Upon information and belief, Teva Pharms. USA is a wholly-owned subsidiary of Teva Pharms. Indus. Ltd.

36. Upon information and belief, Defendant West-Ward Pharm. is a corporation organized and existing under the laws of Delaware, having a principal place of business at 401 Industrial Way West, Eatontown, NJ 07724. Upon information and belief, West-Ward Pharm. is registered with the State of New Jersey's Division of Revenue and Enterprise Services as a business operating in New Jersey under Business ID No. 0100487525, and has appointed The Corporation Trust Company, 820 Bear Tavern Road, West Trenton, NJ, 08628, as its registered agent for service of process in New Jersey. Upon information and belief, West-Ward Pharm. is

registered with the State of New Jersey's Department of Health as a drug Manufacturer and Wholesaler, under Registration No. 5002130.

37. Upon information and belief, West-Ward Pharm. is the authorized U.S. agent for Hikma Pharmaceuticals.

38. Upon information and belief, Defendant Arab Pharm. Manuf. Co. is a corporation organized and existing under the laws of Jordan with a principal place of business at Al-Salt P.O. Box 1695, Amman, Jordan.

39. Upon information and belief, Defendant Hikma Pharms. LLC is a company organized and existing under the laws of Jordan, having a principal place of business in Bayader Wadi Seer, P.O. Box 182400, Amman 1118, Jordan.

40. Upon information and belief, Defendant Hikma Pharms. PLC is a company organized and existing under the laws of the United Kingdom, having a principal place of business at 13 Hanover Square, London W1S 1HL United Kingdom.

41. Upon information and belief, West-Ward Pharm. is a wholly-owned subsidiary of Hikma Pharms. PLC.

42. Upon information and belief, Arab Pharm. Manuf. Co. is a wholly-owned subsidiary of Hikma Pharms. PLC.

43. Upon information and belief, Hikma Pharms. LLC is a wholly-owned subsidiary of Hikma Pharms. PLC.

44. Upon information and belief, Defendant Wockhardt Bio is a company organized and existing under the laws of Switzerland, having a principal place of business at Grafenauweg 6, 6300 Zug, Switzerland.

45. Upon information and belief, Defendant Wockhardt USA is a limited liability company organized and existing under the laws of Delaware, having a principal place of business at 20 Waterview Boulevard, Parsippany, NJ 07054. Upon information and belief, Wockhardt USA is registered with the State of New Jersey's Division of Revenue and Enterprise Services as a business operating in New Jersey under Business ID No. 0400253104, and has appointed The Corporation Service Company, 830 Bear Tavern Road, West Trenton, NJ, 08628, as its registered agent for service of process in New Jersey. Upon information and belief, Wockhardt USA is registered with the State of New Jersey's Department of Health as a drug Wholesaler, under Registration No. 5003430.

46. Upon information and belief, Defendant Wockhardt Ltd. is a company organized and existing under the laws of India, having a principal place of business at Bandra-Kurla Complex, Bandra East, Mumbai 400 051, Maharashtra, India.

47. Upon information and belief, Wockhardt USA is a wholly-owned subsidiary of Wockhardt Bio.

48. Upon information and belief, Wockhardt USA is the authorized U.S. agent for Wockhardt Bio.

49. Upon information and belief, Wockhardt Bio is a wholly-owned subsidiary of Wockhardt Ltd.

50. Upon information and belief, Defendant Hetero USA is a corporation organized and existing under the laws of Delaware, having its principal place of business at 1035 Centennial Avenue, Piscataway, NJ 08854. Upon information and belief, Hetero USA is registered with the State of New Jersey's Division of Revenue and Enterprise Services as a business operating in New Jersey under Business ID No. 0400362826, and has appointed Mr.

Seshu Srinivas Akula, 40 Rouserway, Hillsborough, NJ 08844, as its registered agent for service of process in New Jersey. Upon information and belief, Hetero USA is registered with the State of New Jersey's Department of Health as a drug Wholesaler, under Registration No. 5004050.

51. Upon information and belief, Defendant Hetero Unit-V is a company organized and existing under the laws of India, having a principal place of business at Polepally Village, Jadcherla Mandal, Mahbubnagar, Andhra Pradesh, India.

52. Upon information and belief, Defendant Hetero Ltd. is a company organized and existing under the laws of India, having a principal place of business at 7-2-A2, Hetero Corporate, Industrial Estates, Sanath Nagar, Hyberabad, Telangana, India.

53. Upon information and belief, Hetero USA is the authorized U.S. agent for Hetero Unit-V.

54. Upon information and belief, Hetero Unit-V is a division of Hetero Ltd.

55. Upon information and belief, Hetero USA is a subsidiary of Hetero Ltd.

THE PATENTS-IN-SUIT

56. The '213 patent, entitled "17-Substituted Steroids Useful in Cancer Treatment," was duly and legally issued by the United States Patent and Trademark Office ("USPTO") on February 18, 1997, naming as inventors Susan E. Barrie, Michael Jarman, Gerard A. Potter, and Ian R. Hardcastle. A copy of the '213 patent is attached hereto as **Exhibit A**.

57. Plaintiff BTG lawfully owns all right, title and interest in the '213 patent, including the right to sue and to recover for past infringement.

58. Plaintiffs Janssen is the exclusive licensee of the '213 patent, holding an exclusive license to make, have made, use, lease, sell and otherwise dispose of products falling within the scope of the '213 patent, with a right to enforce the '213 patent.

59. The ’438 patent, entitled “Methods and Compositions for Treating Cancer,” was duly issued by the USPTO on September 2, 2014, naming as inventors Alan H. Auerbach and Arie S. Belldegrun. A copy of the ‘438 patent is attached hereto as **Exhibit B**.

60. Plaintiff Janssen Oncology lawfully owns all right, title and interest in the ’438 patent, including the right to sue and to recover for past infringement.

JANSSEN’S ZYTIGA® (ABIRATERONE ACETATE) TABLETS

61. Janssen sells ZYTIGA® (abiraterone acetate) in the United States pursuant to a New Drug Application (“NDA”) No. 202379 that has been approved by the FDA. Janssen Biotech is the holder of NDA No. 202379. Janssen R&D works in collaboration with Janssen Biotech with respect to NDA No. 202379.

62. ZYTIGA® (abiraterone acetate) is indicated in combination with prednisone for the treatment of patients with metastatic castration-resistant prostate cancer.

63. The FDA issues a publication entitled “Approved Drug Products with Therapeutic Equivalence Evaluations” (the “Orange Book”).

64. In accordance with 21 U.S.C. § 355(b)(1), the ’213 patent is listed in the Orange Book in connection with NDA No. 202379 as a patent “with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug” ZYTIGA® (abiraterone acetate).

65. In accordance with 21 U.S.C. § 355(b)(1), the ’438 patent is listed in the Orange Book in connection with NDA No. 202379 as a patent “with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug” ZYTIGA® (abiraterone acetate).

ACTAVIS'S ANDA SUBMISSION

66. By letter dated June 22, 2015 (the "Actavis Notice Letter"), Actavis Labs. FL notified Plaintiffs that it had submitted to the FDA ANDA No. 208274 ("Actavis ANDA") for Actavis's Abiraterone Acetate Tablets, a drug product that is a generic version of ZYTIGA® (abiraterone acetate) ("Actavis's ANDA Product").

67. Upon information and belief, the purpose of Actavis's ANDA was to obtain approval under the Federal Food, Drug, and Cosmetic Act ("FDCA") to engage in the commercial manufacture, use, and/or sale of Actavis's ANDA Product prior to the expiration of the '213 and '438 patents.

68. In the Actavis Notice Letter, Actavis Labs. FL notified Plaintiffs that, as part of its ANDA, Actavis had filed certifications of the type described in Section 505(j)(2)(A)(vii)(IV) of the FDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV), with respect to the '213 and '438 patents. Upon information and belief, Actavis submitted ANDA No. 208274 to the FDA containing a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that the '213 and '438 patents are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, offer for sale, or sale of Actavis's ANDA Product.

69. The use of Actavis's ANDA Product is covered by one or more claims of the '213 patent.

70. Actavis had knowledge of the '213 patent when it submitted the Actavis ANDA.

71. The use of Actavis's ANDA Product is covered by one or more claims of the '438 patent.

72. Actavis had knowledge of the '438 patent when it submitted the Actavis ANDA.

73. This action is being commenced before the expiration of forty-five days from the date Plaintiffs received the Actavis Notice letter, which Plaintiffs received on or about June 23, 2015.

AMNEAL'S ANDA SUBMISSION

74. By letter dated July 10, 2015 (the "Amneal Notice Letter"), Amneal Pharms. LLC notified Janssen that it had submitted to the FDA ANDA No. 208327 ("Amneal ANDA") for Amneal's Abiraterone Acetate Tablets, a drug product that is a generic version of ZYTIGA® (abiraterone acetate) ("Amneal's ANDA Product").

75. Upon information and belief, Amneal Pharms. NY submitted ANDA No. 208327, alone, together with, and/or on behalf of Amneal Pharms. LLC.

76. Upon information and belief, the purpose of Amneal's ANDA was to obtain approval under the FDCA to engage in the commercial manufacture, use, and/or sale of Amneal's ANDA Product prior to the expiration of the '438 patent.

77. In the Amneal Notice Letter, Amneal Pharms LLC notified Janssen that, as part of its ANDA, Amneal had filed certifications of the type described in Section 505(j)(2)(A)(vii)(IV) of the FDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV), with respect to the '438 patent. Upon information and belief, Amneal submitted ANDA No. 208327 to the FDA containing a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that the '438 patent is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, offer for sale, or sale of Amneal's ANDA Product.

78. The use of Amneal's ANDA Product is covered by one or more claims of the '438 patent.

79. Amneal had knowledge of the '438 patent when it submitted the Amneal ANDA.

80. This action is being commenced before the expiration of forty-five days from the date Janssen received the Amneal Notice letter, which Janssen received on or about July 13, 2015.

APOTEX'S ANDA SUBMISSION

81. By letter dated July 7, 2015 (the "Apotex Notice Letter"), Apotex Inc. and Apotex Corp. notified Janssen that Apotex had submitted to the FDA ANDA No. 208453 ("Apotex ANDA") for Apotex's Abiraterone Acetate Tablets, a drug product that is a generic version of ZYTIGA® (abiraterone acetate) ("Apotex's ANDA Product").

82. Upon information and belief, the purpose of Apotex's ANDA was to obtain approval under the FDCA to engage in the commercial manufacture, use, and/or sale of Apotex's ANDA Product prior to the expiration of the '438 patent.

83. In the Apotex Notice Letter, Apotex notified Janssen that, as part of its ANDA, Apotex had filed certifications of the type described in Section 505(j)(2)(A)(vii)(IV) of the FDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV), with respect to the '438 patent. Upon information and belief, Apotex submitted ANDA No. 208453 to the FDA containing a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that the '438 patent is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, offer for sale, or sale of Apotex's ANDA Product.

84. The use of Apotex's ANDA Product is covered by one or more claims of the '438 patent.

85. Apotex had knowledge of the '438 patent when it submitted the Apotex ANDA.

86. This action is being commenced before the expiration of forty-five days from the date Janssen received the Apotex Notice letter, which Janssen received on or about July 8, 2015.

CITRON PHARMA'S ANDA SUBMISSION

87. By letter dated June 25, 2015 (the "Citron Pharma Notice Letter"), Citron Pharma notified Janssen that it had submitted to the FDA ANDA No. 208371 ("Citron Pharma ANDA") for Citron Pharma's Abiraterone Acetate Tablets, a drug product that is a generic version of ZYTIGA® (abiraterone acetate) ("Citron Pharma's ANDA Product").

88. Upon information and belief, the purpose of Citron Pharma's ANDA was to obtain approval under the FDCA to engage in the commercial manufacture, use, and/or sale of Citron Pharma's ANDA Product prior to the expiration of the '438 patent.

89. In the Citron Pharma Notice Letter, Citron Pharma notified Janssen that, as part of its ANDA, Citron Pharma had filed certifications of the type described in Section 505(j)(2)(A)(vii)(IV) of the FDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV), with respect to the '438 patent. Upon information and belief, Citron Pharma submitted ANDA No. 208371 to the FDA containing a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that the '438 patent is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, offer for sale, or sale of Citron Pharma's ANDA Product.

90. The use of Citron Pharma's ANDA Product is covered by one or more claims of the '438 patent.

91. Citron Pharma had knowledge of the '438 patent when it submitted the Citron ANDA.

92. This action is being commenced before the expiration of forty-five days from the date Janssen received the Citron Pharma Notice letter, which Janssen received on or about June 26, 2015.

DRL'S ANDA SUBMISSION

93. By letter dated July 9, 2015 (the "DRL Notice Letter"), DRL Inc. notified Janssen that DRL Ltd. and DRL Inc. had submitted to the FDA ANDA No. 208416 ("DRL ANDA") for DRL's Abiraterone Acetate Tablets, a drug product that is a generic version of ZYTIGA® (abiraterone acetate) ("DRL's ANDA Product").

94. Upon information and belief, the purpose of DRL's ANDA was to obtain approval under the FDCA to engage in the commercial manufacture, use, and/or sale of DRL's ANDA Product prior to the expiration of the '438 patent.

95. In the DRL Letter, DRL Inc. notified Janssen that, as part of its ANDA, DRL had filed certifications of the type described in Section 505(j)(2)(A)(vii)(IV) of the FDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV), with respect to the '438 patent. Upon information and belief, DRL submitted ANDA No. 208416 to the FDA containing a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that the '438 patent is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, offer for sale, or sale of DRL's ANDA Product.

96. The use of DRL's ANDA Product is covered by one or more claims of the '438 patent.

97. DRL had knowledge of the '438 patent when it submitted the DRL ANDA.

98. This action is being commenced before the expiration of forty-five days from the date Janssen received the DRL Notice letter, which Janssen received on or about July 11, 2015.

MYLAN'S ANDA SUBMISSION

99. By letter dated July 9, 2015 (the "Mylan Notice Letter"), Mylan Pharms. notified Janssen that it had submitted to the FDA ANDA No. 208446 ("Mylan ANDA") for Mylan's

Abiraterone Acetate Tablets, a drug product that is a generic version of ZYTIGA® (abiraterone acetate) ("Mylan's ANDA Product").

100. Upon information and belief, the purpose of Mylan's ANDA was to obtain approval under the FDCA to engage in the commercial manufacture, use, and/or sale of Mylan's ANDA Product prior to the expiration of the '438 patent.

101. In the Mylan Notice Letter, Mylan Pharms. notified Janssen that, as part of its ANDA, Mylan had filed certifications of the type described in Section 505(j)(2)(A)(vii)(IV) of the FDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV), with respect to the '438 patent. Upon information and belief, Mylan submitted ANDA No. 208446 to the FDA containing a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that the '438 patent is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, offer for sale, or sale of Mylan's ANDA Product.

102. The use of Mylan's ANDA Product is covered by one or more claims of the '438 patent.

103. Mylan had knowledge of the '438 patent when it submitted the Mylan ANDA.

104. This action is being commenced before the expiration of forty-five days from the date Janssen received the Mylan Notice letter, which Janssen received on or about July 10, 2015.

PAR'S ANDA SUBMISSION

105. By letter dated June 26, 2015 (the "Par Notice Letter"), Par Pharm. Inc. notified Janssen that it had submitted to the FDA ANDA No. 208168 ("Par ANDA") for Par's Abiraterone Acetate Tablets, a drug product that is a generic version of ZYTIGA® (abiraterone acetate) ("Par's ANDA Product").

106. Upon information and belief, the purpose of Par's ANDA was to obtain approval under the FDCA to engage in the commercial manufacture, use, and/or sale of Par's ANDA Product prior to the expiration of the '438 patent.

107. In the Par Notice Letter, Par Pharm. Inc. notified Janssen that, as part of its ANDA, Par had filed certifications of the type described in Section 505(j)(2)(A)(vii)(IV) of the FDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV), with respect to the '438 patent. Upon information and belief, Par submitted ANDA No. 208168 to the FDA containing a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that the '438 patent is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, offer for sale, or sale of Par's ANDA Product.

108. The use of Par's ANDA Product is covered by one or more claims of the '438 patent.

109. Par had knowledge of the '438 patent when it submitted the Par ANDA.

110. This action is being commenced before the expiration of forty-five days from the date Janssen received the Par Notice letter, which Janssen received on or about June 29, 2015.

SUN'S ANDA SUBMISSION

111. By letter dated June 25, 2015 (the "Sun Notice Letter"), Sun Ltd. notified Janssen that it had submitted to the FDA ANDA No. 208440 ("Sun ANDA") for Sun's Abiraterone Acetate Tablets, a drug product that is a generic version of ZYTIGA® (abiraterone acetate) ("Sun's ANDA Product").

112. Upon information and belief, the purpose of Sun's ANDA was to obtain approval under the FDCA to engage in the commercial manufacture, use, and/or sale of Sun's ANDA Product prior to the expiration of the '438 patent.

113. In the Sun Notice Letter, Sun Ltd. notified Janssen that, as part of its ANDA, Sun had filed certifications of the type described in Section 505(j)(2)(A)(vii)(IV) of the FDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV), with respect to the '438 patent. Upon information and belief, Sun submitted ANDA No. 208440 to the FDA containing a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that the '438 patent is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, offer for sale, or sale of Sun's ANDA Product.

114. The use of Sun's ANDA Product is covered by one or more claims of the '438 patent.

115. Sun had knowledge of the '438 patent when it submitted the Sun ANDA.

116. This action is being commenced before the expiration of forty-five days from the date Janssen received the Sun Notice letter, which Janssen received on or about June 26, 2015.

TEVA'S ANDA SUBMISSION

117. By letter dated July 7, 2015 (the "Teva Notice Letter"), Teva Pharms. USA notified Janssen that it had submitted to the FDA ANDA No. 208432[14] ("Teva ANDA") for Teva's Abiraterone Acetate Tablets, a drug product that is a generic version of ZYTIGA® (abiraterone acetate) ("Teva's ANDA Product").

118. Upon information and belief, the purpose of Teva's ANDA was to obtain approval under the FDCA to engage in the commercial manufacture, use, and/or sale of Teva's ANDA Product prior to the expiration of the '438 patent.

119. In the Teva Notice Letter, Teva Pharms. USA notified Janssen that, as part of its ANDA, Teva had filed certifications of the type described in Section 505(j)(2)(A)(vii)(IV) of the

[14] By letter dated August 31, 2015, Teva informed Plaintiffs that the correct number of Teva's ANDA for generic abiraterone acetate products is 208432.

FDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV), with respect to the '438 patent. Upon information and belief, Teva submitted ANDA No. 208432 to the FDA containing a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that the '438 patent is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, offer for sale, or sale of Teva's ANDA Product.

120. The use of Teva's ANDA Product is covered by one or more claims of the '438 patent.

121. Teva had knowledge of the '438 patent when it submitted the Teva ANDA.

122. This action is being commenced before the expiration of forty-five days from the date Janssen received the Teva Notice letter, which Janssen received on or about July 8, 2015.

HIKMA/WEST-WARD'S ANDA SUBMISSION

123. By letter dated June 24, 2015 (the "Hikma/West-Ward Notice Letter"), West-Ward notified Janssen that, as U.S. agent for Hikma Pharmaceuticals, it had submitted to the FDA ANDA No. 208339 ("Hikma/West-Ward ANDA") for Hikma/West-Ward's Abiraterone Acetate Tablets, a drug product that is a generic version of ZYTIGA® (abiraterone acetate) ("Hikma/West-Ward's ANDA Product").

124. Upon information and belief, the purpose of Hikma/West-Ward's ANDA was to obtain approval under the FDCA to engage in the commercial manufacture, use, and/or sale of Hikma/West-Ward's ANDA Product prior to the expiration of the '438 patent.

125. In the Hikma/West-Ward Notice Letter, West-Ward notified Janssen that, as part of its ANDA, Hikma/West-Ward had filed certifications of the type described in Section 505(j)(2)(A)(vii)(IV) of the FDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV), with respect to the '438 patent. Upon information and belief, Hikma/West-Ward submitted ANDA No. 208339 to the

FDA containing a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that the '438 patent is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, offer for sale, or sale of Hikma/West-Ward's ANDA Product.

126. The use of Hikma/West-Ward's ANDA Product is covered by one or more claims of the '438 patent.

127. Hikma/West-Ward had knowledge of the '438 patent when it submitted the Hikma/West-Ward ANDA.

128. This action is being commenced before the expiration of forty-five days from the date Janssen received the Hikma/West-Ward Notice letter, which Janssen received on or about June 25, 2015.

WOCKHARDT'S ANDA SUBMISSION

129. By letter dated June 24, 2015 (the "Wockhardt Notice Letter"), Wockhardt Bio notified Janssen that it had submitted to the FDA ANDA No. 208380 ("Wockhardt ANDA") for Wockhardt's Abiraterone Acetate Tablets, a drug product that is a generic version of ZYTIGA® (abiraterone acetate) ("Wockhardt's ANDA Product").

130. Upon information and belief, the purpose of Wockhardt's ANDA was to obtain approval under the FDCA to engage in the commercial manufacture, use, and/or sale of Wockhardt's ANDA Product prior to the expiration of the '438 patent.

131. In the Wockhardt Notice Letter, Wockhardt Bio notified Janssen that, as part of its ANDA, Wockhardt had filed certifications of the type described in Section 505(j)(2)(A)(vii)(IV) of the FDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV), with respect to the '438 patent. Upon information and belief, Wockhardt submitted ANDA No. 208380 to the FDA containing a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that the '438

patent is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, offer for sale, or sale of Wockhardt's ANDA Product.

132. The use of Wockhardt's ANDA Product is covered by one or more claims of the '438 patent.

133. Wockhardt had knowledge of the '438 patent when it submitted the Wockhardt ANDA.

134. This action is being commenced before the expiration of forty-five days from the date Janssen received the Wockhardt Notice letter, which Janssen received on or about June 25, 2015.

HETERO'S ANDA SUBMISSION

135. By letter dated August 28, 2015 (the "Hetero Notice Letter"), Hetero USA notified Janssen that Hetero had submitted to the FDA ANDA No. 208349 ("Hetero ANDA") for Hetero's Abiraterone Acetate Tablets, a drug product that is a generic version of ZYTIGA® (abiraterone acetate) ("Hetero's ANDA Product").

136. Upon information and belief, the purpose of Hetero's ANDA was to obtain approval under the FDCA to engage in the commercial manufacture, use, and/or sale of Hetero's ANDA Product prior to the expiration of the '438 patent.

137. In the Hetero Notice Letter, Hetero USA notified Janssen that, as part of Hetero's ANDA, Hetero had filed certifications of the type described in Section 505(j)(2)(A)(vii)(IV) of the FDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV), with respect to the '438 patent. Upon information and belief, Hetero submitted ANDA No. 208349 to the FDA containing a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that the '438 patent is invalid, unenforceable,

and/or will not be infringed by the commercial manufacture, use, offer for sale, or sale of Hetero's ANDA Product.

138. The use of Hetero's ANDA Product is covered by one or more claims of the '438 patent.

139. Hetero had knowledge of the '438 patent when it submitted the Hetero ANDA.

140. This action is being commenced before the expiration of forty-five days from the date Janssen received the Hetero Notice letter, which Janssen received on or about August 31, 2015.

SUBJECT MATTER JURISDICTION AND VENUE

141. This action for patent infringement arises under 35 U.S.C. § 100 *et seq.* generally and 35 U.S.C. § 271(e)(2) specifically.

142. This Court has jurisdiction over the subject matter of this action pursuant to the provisions of 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

143. Venue is proper in this judicial district pursuant to the provisions of 28 U.S.C. §§ 1391 and 1400(b).

PERSONAL JURISDICTION

Defendant Actavis

144. Upon information and belief, Actavis Labs. FL is in the business of formulating, manufacturing, marketing, and selling generic prescription pharmaceutical drugs that it distributes in New Jersey and throughout the United States.

145. This Court has personal jurisdiction over Actavis Labs. FL by virtue of the fact that, *inter alia*, Actavis Labs FL has committed a tortious act of patent infringement under 35 U.S.C. § 271(e)(2), and intends a future course of conduct that includes acts of patent

infringement in New Jersey. These acts have led and will lead to foreseeable harm and injury to Plaintiffs, including to Plaintiff Janssen R&D, a New Jersey resident corporation, in New Jersey. For example, upon information and belief, Actavis Labs. FL is actively preparing to make the proposed generic copies of ZYTIGA® (abiraterone acetate) that are the subject of Actavis's ANDA No. 208274, and to use, sell, and offer for sale such generic copies in this State and this judicial district.

146. Upon information and belief, Actavis Labs. FL has substantial, continuous and systematic contacts with New Jersey, including, *inter alia*, having a principal place of business in Parsippany, New Jersey.

147. Upon information and belief, Actavis Labs. FL has previously submitted to the jurisdiction of this Court and asserted counterclaims in this jurisdiction. *See, e.g.*, *Supernus Pharms., Inc. v. Actavis Inc., et al.*, No. 15-cv-02499; *Orexo AB v. Actavis Labs. FL, Inc.*, No. 3:15-cv-00826; *Astrazeneca Ab et al. v. Actavis Labs. FL, Inc., et al.*, No. 3:14-cv-07870; *Astrazeneca Ab et al. v. Actavis Labs. FL, Inc., et al.*, No. 3:14-cv-07263; *Noven Therapeutics, LLC v. Actavis Labs. FL, Inc., et al.*, No. 2:14-cv-06414; and *Vivus, Inc. v. Actavis Labs. FL, Inc.*, No. 2:14-cv-03786.

148. Upon information and belief, Actavis Pharma is an integrated pharmaceutical company engaged in the development, manufacturing, marketing, selling and distribution of generic prescription pharmaceutical drugs, including products made by Actavis Labs. FL, in New Jersey and throughout the United States.

149. Upon information and belief, Actavis Pharma has substantial, continuous and systematic contacts with New Jersey, including having a principal place of business in

Parsippany, New Jersey, and it has registered to do business in New Jersey and appointed a registered agent for service of process in New Jersey.

150. Upon information and belief, Actavis Pharma has previously submitted to the jurisdiction of this Court. *See, e.g. AstraZeneca AB et al. v. Actavis Labs. FL, Inc., et al.*, No. 3:14-cv-07263; *Noven Therapeutics, LLC v. Actavis Labs. FL, Inc., et al.*, No. 2:14-cv-06414; *Supernus Pharms., Inc. v. Actavis, Inc., et al.*, No. 14-cv-01981; and *Cipher Pharms., Inc., et al. v. Watson Labs., Inc., et al.*, No. 1:13-cv-06502.

151. Upon information and belief, Actavis, Inc. is in the business of, *inter alia*, the development, manufacture, marketing, sale, and distribution of generic pharmaceutical products, in New Jersey and throughout the United States, through its various subsidiaries, including Actavis Labs. FL and Actavis Pharma.

152. Upon information and belief, Actavis Inc. has substantial, continuous and systematic contacts with New Jersey, including having a principal place of business in New Jersey.

153. Upon information and belief, Actavis Inc. has previously submitted to the jurisdiction of this Court and asserted counterclaims in this jurisdiction. *See, e.g., Noven Therapeutics, LLC v. Actavis Labs. FL, Inc., et al.*, No. 2:14-cv-06414; *Cipher Pharms., Inc., et al. v. Watson Labs., Inc., et al.*, No. 1:13-cv-06502; *Abbott Labs., et al. v. Actavis Elizabeth LLC, et al.*, No. 2:10-cv-02352; and *Warner Chilcott Labs. Ireland Ltd., et al. v. Actavis Elizabeth LLC, et al.*, No. 2:09-cv-00469.

154. Upon information and belief, Actavis Labs. FL, Actavis Pharma, and Actavis, Inc. hold themselves out as a single entity for the purposes of manufacturing, selling, marketing,

distribution, and importation of generic drug products in New Jersey and throughout the United States.

155. On information and belief, Actavis Labs. FL, Actavis Pharma, and Actavis, Inc. are agents of each other with respect to formulating, manufacturing, packaging, marketing and/or selling pharmaceutical products throughout the United States and will do the same with respect to Actavis's ANDA Product for which they have sought approval from the FDA.

156. On information and belief, Actavis Labs. FL, Actavis Pharma, and Actavis, Inc. are acting in concert with each other with respect to formulating, manufacturing, packaging, marketing and/or selling pharmaceutical products throughout the United States and will do the same with respect to Actavis's ANDA Product for which they have sought approval from the FDA.

157. Upon information and belief, Actavis Pharma and Actavis, Inc., together with their affiliate and/or agent, Actavis Labs. FL, filed the Actavis ANDA with the FDA that is at issue in this patent infringement suit.

158. Upon information and belief, Actavis Pharma and Actavis, Inc., alone and/or together with their affiliate and/or agent Actavis Labs. FL, have committed, or aided, abetted, actively induced, contributed to, or participated in the commission of an act of patent infringement under 35 U.S.C. § 271(e)(2) that has led and/or will lead to foreseeable harm and injury to Plaintiffs, including to Janssen R&D, which is a New Jersey company, in New Jersey.

159. This Court has personal jurisdiction over Actavis Labs. FL by virtue of, among other things, (1) its continuous and systematic contacts with New Jersey, including its principal place of business in Parsippany, NJ; (2) its tortious acts of patent infringement that will result in foreseeable harm in New Jersey; (3) its sale of a substantial volume of prescription drugs in New

Jersey; (4) its purposefully availing itself of the jurisdiction of this court in the past; and (5) its conduct by, through, and in concert with Actavis Pharma and Actavis, Inc.

160. This Court has personal jurisdiction over Actavis Pharma by virtue of, among other things, (1)) its continuous and systematic contacts with New Jersey, including its principal place of business in Parsippany, NJ; (2) its consent to jurisdiction in New Jersey by its registration to do business in New Jersey and appointment of registered agent in New Jersey for the receipt of service of process; (3) its tortious acts of patent infringement that will result in foreseeable harm in New Jersey; (4) its sale of a substantial volume of prescription drugs in New Jersey; (5) its purposefully availing itself of the jurisdiction of this court in the past; and (6) its conduct by, through, and in concert with Actavis Labs. FL and Actavis, Inc.

161. This Court has personal jurisdiction over Actavis, Inc. by virtue of, among other things, (1) its continuous and systematic contacts with New Jersey, including its principal place of business in Parsippany, NJ; (2) its tortious acts of patent infringement that will result in foreseeable harm in New Jersey; (3) its sale of a substantial volume of prescription drugs in New Jersey; (4) its purposefully availing itself of the jurisdiction of this court in the past; and (5) its conduct by, through, and in concert with Actavis Labs. FL and Actavis Pharma.

Defendant Amneal

162. Upon information and belief, Amneal Pharms. LLC is in the business of formulating, manufacturing, marketing, and selling generic prescription pharmaceutical drugs that it distributes in New Jersey and throughout the United States.

163. Amneal Pharms. LLC's website states that its generic product pipeline is "[d]riven through five proprietary research and development facilities located in New York, New

Jersey and India . . . ."[15] Amneal Pharms. LLC's website identifies, *inter alia*, the following locations in the United States: (1) U.S. Corporate Headquarters in Bridgewater, NJ; (2) Oral Solids Manufacturing in Paterson, NJ; and (3) Oral Solids Manufacturing and R&D in Brookhaven, NY and Hauppauge, NY.[16]

164. This Court has personal jurisdiction over Amneal Pharms. LLC and/or Amneal Pharms. NY by virtue of the fact that, *inter alia*, Amneal Pharms. LLC and/or Amneal Pharms. NY has committed a tortious act of patent infringement under 35 U.S.C. § 271(e)(2), and intends a future course of conduct that includes acts of patent infringement in New Jersey. These acts have led and will lead to foreseeable harm and injury to Janssen, including to Plaintiff Janssen R&D, a New Jersey resident corporation, in New Jersey. For example, upon information and belief, Amneal Pharms. LLC is actively preparing to make the proposed generic copies of ZYTIGA® (abiraterone acetate) that are the subject of Amneal's ANDA No. 208327, and to use, sell, and offer for sale such generic copies in this State and this judicial district.

165. Upon information and belief, Amneal Pharms. LLC has substantial, continuous and systematic contacts in New Jersey, including, *inter alia*, having a principal place of business in New Jersey, and it has registered to do business in New Jersey, appointed a registered agent for service of process in New Jersey, and registered as a manufacturer and wholesaler of drugs in New Jersey.

166. Upon information and belief, Amneal Pharms. LLC has previously submitted to the jurisdiction of this Court and has asserted counterclaims in this jurisdiction. *See, e.g.*, *Shire*

[15] *See* http://amneal.com/products/pipeline/ (last visited July 17, 2015).

[16] *See* http://amneal.com/about/locations/ (last visited July 17, 2015).

Dev. LLC, et al. v. Amneal Pharms. LLC, et al., No. 1:15-cv-02865; *Otsuka Pharm. Co., Ltd. v. Amneal Pharms. LLC, et al*., No. 1:15-cv-01585.

167. Upon information and belief, Amneal Pharms. NY, either directly or through Amneal Pharms. LLC is in the business of formulating, manufacturing, marketing, and selling generic prescription pharmaceutical drugs that it distributes in New Jersey and throughout the United States.

168. Upon information and belief, Amneal Pharms. NY, either directly or through Amneal Pharms. LLC, has substantial, continuous and systematic contacts with New Jersey, and it has registered as a drug manufacturer in New Jersey.

169. Upon information and belief, Amneal Pharms. NY has previously submitted to the jurisdiction of this Court, and has asserted counterclaims in this jurisdiction. *See, e.g.*, *Shire Dev. LLC, et al. v. Amneal Pharms. LLC, et al.*, No. 1:15-cv-02865.

170. Upon information and belief, Amneal Pharms. LLC and Amneal Pharms. NY hold themselves out as a single entity for the purposes of manufacturing, selling, marketing, distribution, and importation of generic drug products in New Jersey and throughout the United States.

171. On information and belief, Amneal Pharms. LLC and Amneal Pharms. NY are agents of each other with respect to formulating, manufacturing, packaging, marketing and/or selling pharmaceutical products throughout the United States and will do the same with respect to Amneal's ANDA Product for which they have sought approval from the FDA.

172. On information and belief, Amneal Pharms. LLC and Amneal Pharms. NY are acting in concert with each other with respect to formulating, manufacturing, packaging, marketing and/or selling pharmaceutical products throughout the United States and will do the

same with respect to Amneal's ANDA Product for which they have sought approval from the FDA.

173. Upon information and belief, Amneal Pharms. LLC, together with its affiliate and/or agent, Amneal Pharms. NY, filed the Amneal ANDA with the FDA that is at issue in this patent infringement suit.

174. Upon information and belief, Amneal Pharms. LLC and Amneal Pharms. NY, alone and/or together have committed, or aided, abetted, actively induced, contributed to, or participated in the commission of an act of patent infringement under 35 U.S.C. § 271(e)(2) that has led and/or will lead to foreseeable harm and injury to Janssen, including Janssen R&D, which is a New Jersey company, in New Jersey.

175. This Court has personal jurisdiction over Amneal Pharms. LLC by virtue of, among other things, (1) its continuous and systematic contacts with New Jersey, including its principal place of business in Bridgewater, NJ and manufacturing facilities in Paterson, NJ; (2) its consent to jurisdiction in New Jersey by its registration to do business in New Jersey and appointment of registered agent in New Jersey for the receipt of service of process; (3) its registration with the State of New Jersey's Department of Health as a drug manufacturer and wholesaler; (4) its tortious acts of patent infringement that will result in foreseeable harm in New Jersey; (5) its sale of a substantial volume of prescription drugs in New Jersey; (6) its purposefully availing itself of the jurisdiction of this court in the past; and (7) its conduct by, through, in concert with Amneal Pharms. NY.

176. This Court has personal jurisdiction over Amneal Pharms. NY by virtue of, among other things, (1) its continuous and systematic contacts with New Jersey; (2) its registration as a drug manufacturer in New Jersey; (3) its tortious acts of patent infringement that

will result in foreseeable harm in New Jersey; (4) its sale of a substantial volume of prescription drugs in New Jersey; (5) its purposefully availing itself of the jurisdiction of this court in the past; and (6) its conduct by, through and in concert with Amneal Pharms. LLC.

Defendant Apotex

177. By email dated July 21, 2015, through their counsel, Apotex Corp. and Apotex Inc. stated that "Apotex will not contest jurisdiction in New Jersey for the purpose of an action under 21 U.S.C. 355(j)(50(B)(iii) relating to its [Paragraph IV] Notice related to ANDA No. 208453."

178. Upon information and belief, Apotex Corp. is in the business of formulating, manufacturing, marketing, and selling generic prescription pharmaceutical drugs that it distributes in New Jersey and throughout the United States.

179. Upon information and belief, Apotex Corp. is the authorized U.S. agent for Apotex Inc.

180. This Court has personal jurisdiction over Apotex Corp. and Apotex Inc. by virtue of the fact that, *inter alia*, they have committed a tortious act of patent infringement under 35 U.S.C. § 271(e)(2), and intend a future course of conduct that includes acts of patent infringement in New Jersey. These acts have led and will lead to foreseeable harm and injury to Janssen, including to Plaintiff Janssen R&D, a New Jersey resident corporation, in New Jersey. For example, upon information and belief, Apotex Corp and Apotex Inc. are actively preparing to make the proposed generic copies of ZYTIGA® (abiraterone acetate) that are the subject of Apotex's ANDA No. 208453, and to use, sell, and offer for sale such generic copies in this State and this judicial district.

181. Upon information and belief, Apotex Corp. has substantial, continuous and systematic contacts with New Jersey, and has registered as a drug wholesaler in New Jersey.

182. Upon information and belief, Apotex Corp. has previously submitted to the jurisdiction of this Court and has asserted counterclaims in this jurisdiction. *See, e.g.*, *Bausch & Lomb Inc., et al. v. Apotex Inc. and Apotex Corp.*, No. 1:14-cv-01975; *Hoffman-La Roche Inc. v. Apotex Inc. and Apotex Corp.*, No. 2:07-cv-04417.

183. Upon information and belief, Apotex Inc., directly or through Apotex Corp., is in the business of formulating, manufacturing, marketing, and selling generic prescription pharmaceutical drugs that it distributes in New Jersey and throughout the United States.

184. Upon information and belief, Apotex Inc. has substantial, continuous and systematic contacts with New Jersey, including, but not limited to, directing the operations and management of Apotex Corp.

185. Upon information and belief, Apotex Inc. has previously submitted to the jurisdiction of this court and has asserted counterclaims in this jurisdiction. *See, e.g., Bausch & Lomb Inc., et al. v. Apotex Inc. and Apotex Corp.*, No. 1:14-cv-01975; *Apotex Inc. v. Shire LLC*, No. 2:08-cv-03598; and *Hoffman-La Roche Inc. v. Apotex Inc. and Apotex Corp.*, No. 2:07-cv-04417.

186. Upon information and belief, Apotex Corp. and Apotex Inc. hold themselves out as a single entity for the purposes of manufacturing, selling, marketing, distribution, and importation of generic drug products in New Jersey and throughout the United States.

187. Upon information and belief, Apotex Corp. and Apotex Inc. are agents of each other with respect to formulating, manufacturing, packaging, marketing and/or selling

pharmaceutical products throughout the United States and will do the same with respect to Apotex's ANDA Product for which they have sought approval from the FDA.

188. On information and belief, Apotex Corp. and Apotex Inc. are acting in concert with each other with respect to formulating, manufacturing, packaging, marketing and/or selling pharmaceutical products throughout the United States and will do the same with respect to Apotex's ANDA Product for which they have sought approval from the FDA.

189. Upon information and belief, Apotex Inc., alone and/or together with its affiliate and agent, Apotex Corp., filed the Apotex ANDA with the FDA that is at issue in this patent infringement suit.

190. Upon information and belief, Apotex Corp., alone and/or together with its affiliate Apotex Inc. has committed, or aided, abetted, actively induced, contributed to, or participated in the commission of an act of patent infringement under 35 U.S.C. § 271(e)(2) that has led and/or will lead to foreseeable harm and injury to Janssen, including to Plaintiff Janssen R&D, which is a New Jersey company, in New Jersey.

191. This Court has personal jurisdiction over Apotex Corp. by virtue of, among other things, (1) its consent to jurisdiction by its express representation that "Apotex will not contest jurisdiction in New Jersey for the purposes of an action under 21 U.S.C. 355(j)(5)(B)(iii) relating to its P-IV notice related to ANDA No. 208453"; (2) its continuous and systematic contacts with New Jersey; (3) its registration as a drug wholesaler in New Jersey; (4) its acts of tortious patent infringement that will result in foreseeable harm in New Jersey; (5) its sale of a substantial volume of prescription drugs in New Jersey; (5) its purposefully availing itself of the jurisdiction of this court in the past; and (6) its conduct by, through, and in concert with Apotex Inc.

192. This Court has personal jurisdiction over Apotex Inc. by virtue of, among other things, (1) its consent to jurisdiction by its express representation that "Apotex will not contest jurisdiction in New Jersey for the purposes of an action under 21 U.S.C. 355(j)(5)(B)(iii) relating to its P-IV notice related to ANDA No. 208453"; (2) its continuous and systematic contacts with New Jersey; (3) its sale of a substantial volume of prescription drugs in New Jersey; (4) its acts of tortious patent infringement that will result in foreseeable harm in New Jersey; (5) its purposefully availing itself of the jurisdiction of this court in the past; and (6) its conduct by, through, and in concert with Apotex Corp.

193. In the alternative, this Court has personal jurisdiction over Apotex Inc. because the requirements of Federal Rule of Civil Procedure 4(k)(2)(A) are met.

Defendant Citron Pharma

194. Upon information and belief, Citron Pharma is in the business of developing and marketing pharmaceutical drugs that it distributes in New Jersey and throughout the United States.

195. Citron Pharma's website further states that Citron Pharma has "FDA-approved manufacturing facilities in India and the USA" and that it is "headquartered at New Jersey."[17]

196. This Court has personal jurisdiction over Citron Pharma by virtue of the fact that, *inter alia*, Citron Pharma has committed a tortious act of patent infringement under 35 U.S.C. § 271(e)(2), and intends a future course of conduct that includes acts of patent infringement in New Jersey. These acts have led and will lead to foreseeable harm and injury to Janssen, including to Plaintiff Janssen R&D, a New Jersey resident corporation, in New Jersey. For

[17]http://www.citronpharma.com/vision-mission-strategy.html (last visited July 20, 2015).

example, upon information and belief, Citron Pharma is actively preparing to make the proposed generic copies of ZYTIGA® (abiraterone acetate) that are the subject of Citron's ANDA No. 208371, and to use, sell, and offer for sale such generic copies in this State and this judicial district.

197. Upon information and belief, Citron Pharma has substantial, continuous and systematic contacts with New Jersey, including, *inter alia*, its incorporation in New Jersey and its principal places of business in New Jersey, and it has registered to do business in New Jersey, appointed a registered agent in New Jersey for receipt of service of process, and registered as a drug wholesaler in New Jersey.

198. Upon information and belief, Citron Pharma has previously submitted to the jurisdiction of this Court and asserted counterclaims in this jurisdiction. *See, e.g., Takeda Gmbh, et al. v. Citron Pharma LLC and MSN Labs. Pvt. Ltd.*, No. 3:15-cv-03383.

199. This Court has personal jurisdiction over Citron Pharma by virtue of, among other things, (1) its continuous and systematic contacts with New Jersey, including its incorporation in New Jersey and its principal places of business in East Brunswick, New Jersey and Holmdel, New Jersey; (2) its consent to jurisdiction in New Jersey by its registration to do business in New Jersey and appointment of registered agent in New Jersey for the receipt of service of process; (3) its registration as a drug wholesaler in New Jersey (4) its tortious acts of patent infringement that will result in foreseeable harm in New Jersey; (5) its purposefully availing itself of the jurisdiction of this court in the past; and (6) its sale of a substantial volume of prescription drugs in New Jersey.

Defendant DRL

200. Upon information and belief, DRL Inc. is in the business of formulating, manufacturing, marketing, and selling generic prescription pharmaceutical drugs that it distributes in New Jersey and throughout the United States.

201. This Court has personal jurisdiction over DRL Ltd. and DRL Inc. by virtue of the fact that, *inter alia*, they have committed a tortious act of patent infringement under 35 U.S.C. § 271(e)(2), and intend a future course of conduct that includes acts of patent infringement in New Jersey. These acts have led and will lead to foreseeable harm and injury to Janssen, including to Plaintiff Janssen R&D, a New Jersey resident corporation, in New Jersey. For example, upon information and belief, DRL Ltd. and DRL Inc. are actively preparing to make the proposed generic copies of ZYTIGA® (abiraterone acetate) that are the subject of DRL's ANDA No. 208416, and to use, sell, and offer for sale such generic copies in this State and this judicial district.

202. Upon information and belief, DRL Inc. has substantial, continuous and systematic contacts with New Jersey, including, *inter alia*, its incorporation in New Jersey and its principal place of business in New Jersey, and it has registered to do business in New Jersey, appointed a registered agent for service of process in New Jersey, and registered as a drug manufacturer and wholesaler in New Jersey.

203. Upon information and belief, DRL Inc. has previously actively litigated in this jurisdiction, submitted to the jurisdiction of this Court, and has asserted counterclaims in this jurisdiction. *See, e.g., Sanofi-Aventis U.S. LLC, et al. v. Dr. Reddy's Labs. Inc. and Dr. Reddy's Labs., Ltd.*, No. 3:15-cv-02522; *Sucampo AG, et al. v. Dr. Reddy's Labs. Inc. and Dr. Reddy's Labs., Ltd.*, No. 3:14-cv-07114; *Dr. Reddy's Labs., Inc. and Dr. Reddy's Labs., Ltd. v. Purdue*

Pharm. Prods. L.P., et al., No. 2:14-cv-03230; and *Dr. Reddy's Labs., Ltd. and Dr. Reddy's Labs., Inc. v. Eli Lilly & Co.*, No. 3:09-cv-00192.

204. Upon information and belief, DRL Inc. is the authorized U.S. agent for DRL Ltd.

205. Upon information and belief, DRL Ltd., directly or through DRL Inc., is in the business of formulating, manufacturing, marketing, and selling generic prescription pharmaceutical drugs that it distributes in New Jersey and throughout the United States.

206. Upon information and belief, DRL Ltd. has substantial, continuous and systematic contacts with New Jersey, directly or through its wholly-owned subsidiary DRL Inc.

207. Upon information and belief, DRL Ltd. maintains research and development facilities in New Jersey, including its Technology Development Centre in Princeton, NJ and Brunswick Research Center in Monmouth Junction, NJ.

208. Upon information and belief, DRL Ltd. has previously actively litigated in this jurisdiction, submitted to the jurisdiction of this Court, and has asserted counterclaims in this jurisdiction. *See, e.g., Sanofi-Aventis U.S. LLC, et al. v. Dr. Reddy's Labs. Inc. and Dr. Reddy's Labs., Ltd.*, No. 3:15-cv-02522; *Sucampo AG, et al. v. Dr. Reddy's Labs. Inc. and Dr. Reddy's Labs., Ltd.*, No. 3:14-cv-07114; *Dr. Reddy's Labs., Inc. and Dr. Reddy's Labs., Ltd. v. Purdue Pharm. Prods. L.P., et al.*, No. 2:14-cv-03230 and *Dr. Reddy's Labs., Ltd. and Dr. Reddy's Labs., Inc. v. Eli Lilly & Co.*, No. 3:09-cv-00192.

209. Upon information and belief, DRL Inc. and DRL Ltd. hold themselves out as a single entity for the purposes of manufacturing, selling, marketing, distribution, and importation of generic drug products in New Jersey and throughout the United States.

210. On information and belief, DRL Inc. and DRL Ltd. are agents of each other with respect to formulating, manufacturing, packaging, marketing and/or selling pharmaceutical

products throughout the United States and will do the same with respect to DRL's ANDA Product for which they have sought approval from the FDA.

211. On information and belief, DRL Inc. and DRL Ltd. are acting in concert with each other with respect to formulating, manufacturing, packaging, marketing and/or selling pharmaceutical products throughout the United States and will do the same with respect to DRL's ANDA Product for which they have sought approval from the FDA.

212. Upon information and belief, DRL Ltd., alone and/or through its affiliate and/or agent, DRL Inc., filed the Apotex ANDA with the FDA that is at issue in this patent infringement suit.

213. Upon information and belief, DRL Inc., alone and/or together with its affiliate DRL Ltd. has committed, or aided, abetted, actively induced, contributed to, or participated in the commission of an act of patent infringement under 35 U.S.C. § 271(e)(2) that has led and/or will lead to foreseeable harm and injury to Janssen, including to Plaintiff Janssen R&D, which is a New Jersey company, in New Jersey.

214. This Court has personal jurisdiction over DRL Inc. by virtue of, among other things, (1) continuous and systematic contacts in New Jersey, including its incorporation in New Jersey and its principal place of business in Princeton, NJ; (2) its consent to jurisdiction in New Jersey by its registration to do business in New Jersey and appointment of registered agent in New Jersey for the receipt of service of process; (3) its registration as a drug manufacturer and wholesaler in New Jersey; (4) its acts of tortious patent infringement that will result in foreseeable harm in New Jersey; (5) its sale of a substantial volume of prescription drugs in New Jersey; (6) its purposefully availing itself of the jurisdiction of this court in the past; and (7) its conduct by and through, and in concert with, DRL. Ltd.

215. This Court has personal jurisdiction over DRL Ltd. by virtue of, among other things, (1) its continuous and systematic contacts with New Jersey, including its research and development facilities in Princeton, New Jersey and Monmouth Junction, New Jersey; (2) its acts of tortious patent infringement that will result in foreseeable harm in New Jersey; (3) its sale of a substantial volume of prescription drugs in New Jersey; (4) its purposefully availing itself of the jurisdiction of this court in the past; and (5) its conduct by and through, and in concert with, DRL Inc.

216. In the alternative, this Court has personal jurisdiction over DRL Ltd. because the requirements of Federal Rule of Civil Procedure 4(k)(2)(A) are met.

Defendant Mylan

217. Upon information and belief, Mylan Pharms. is in the business of formulating, manufacturing, marketing, and selling generic prescription pharmaceutical drugs that it distributes in New Jersey and throughout the United States.

218. This Court has personal jurisdiction over Mylan Pharms. by virtue of the fact that, *inter alia*, it has committed a tortious act of patent infringement under 35 U.S.C. § 271(e)(2), and intends a future course of conduct that includes acts of patent infringement in New Jersey. These acts have led and will lead to foreseeable harm and injury to Janssen, including Plaintiff Janssen R&D, a New Jersey resident corporation, in New Jersey. For example, upon information and belief, Mylan Pharms. is actively preparing to make the proposed generic copies of ZYTIGA® (abiraterone acetate) that are the subject of Mylan's ANDA No. 208446, and to use, sell, and offer for sale such generic copies in this State and this judicial district.

219. Upon information and belief, Mylan Pharms. has substantial, continuous and systematic contacts with New Jersey, and it is registered to do business in New Jersey, has

appointed a registered agent in New Jersey for receipt of service of process, and is registered as a drug manufacturer and wholesaler in New Jersey.

220. Upon information and belief, Mylan Pharms. has previously actively litigated in this jurisdiction, submitted to the jurisdiction of this Court, and asserted counterclaims in this jurisdiction. *See, e.g., Mylan Inc., et al. v. SmithKline Beecham Corp., et al.*, No. 3:10-cv-04809; *Mylan Inc., et al. v. Apotex Inc., et al.*, No. 3:14-cv-04560; *Warner Chilcott Co., LLC v. Mylan Inc., et al.*, No. 13-cv-06560; *Aptalis Pharma US Inc., et al. v. Mylan Pharms. Inc., et al.*, No. 3:13-cv-04158.

221. Upon information and belief, Mylan Inc., directly or through Mylan Pharms., is in the business of formulating, manufacturing, marketing, and selling generic prescription pharmaceutical drugs that it distributes in New Jersey and throughout the United States.

222. Upon information and belief, Mylan Inc. has substantial, continuous and systematic contacts with New Jersey, including the direction of operations and management of Mylan Pharms., and it is registered to do business in New Jersey and has appointed a registered agent in New Jersey for receipt of service of process in New Jersey.

223. Upon information and belief, Mylan Inc. owns a subsidiary, Mylan Specialty, located at 110 Allen Rd., Basking Ridge, New Jersey 07920.

224. Upon information and belief, Mylan Inc. has previously actively litigated in this jurisdiction, submitted to the jurisdiction of this Court, and has asserted counterclaims in this jurisdiction. *See, .e.g., Mylan Inc., et al. v. SmithKline Beecham Corp., et al.*, No. 3:10-cv-04809; *Mylan Inc., et al. v. Apotex Inc., et al.*, No. 3:14-cv-04560; *Aptalis Pharma US Inc., et al. v. Mylan Pharms. Inc., et al.*, No. 3:13-cv-04158.

225. Upon information and belief, Mylan Pharms. and Mylan Inc. hold themselves out as a single entity for the purposes of manufacturing, selling, marketing, distribution, and importation of generic drug products in New Jersey and throughout the United States. Upon information and belief, Mylan Inc.'s website describes Mylan Inc. and its subsidiaries as a company "with true vertical integration."[18]

226. On information and belief, Mylan Pharms. and Mylan Inc. are agents of each other with respect to formulating, manufacturing, packaging, marketing and/or selling pharmaceutical products throughout the United States and will do the same with respect to Mylan's ANDA Product for which they have sought approval from the FDA.

227. On information and belief, Mylan Pharms. and Mylan Inc. are acting in concert with each other with respect to formulating, manufacturing, packaging, marketing and/or selling pharmaceutical products throughout the United States and will do the same with respect to Mylan's ANDA Product for which they have sought approval from the FDA.

228. Upon information and belief, Mylan Inc., together with its affiliate and/or agent, Mylan Pharms., filed the Mylan ANDA with the FDA that is at issue in this patent infringement suit.

229. Upon information and belief, Mylan Inc. alone and/or together with its affiliate and/or agent Mylan Pharms. has committed, or aided, abetted, actively induced, contributed to, or participated in the commission of an act of patent infringement under 35 U.S.C. § 271(e)(2) that has led and/or will lead to foreseeable harm and injury to Janssen, including to Janssen R&D, which is a New Jersey company, in New Jersey.

[18]http://www.mylan.com/en/company/about-us (last visited July 21, 2015).

230. This Court recently denied a Motion to Dismiss for lack of personal jurisdiction by Mylan Inc. and Mylan Pharms., finding that the Court "may exercise general jurisdiction over Mylan Inc. and Mylan [Pharms.]." *Otsuka Pharm. Co., Ltd. v. Mylan Inc., et al.*, No. 1:14-cv-04508, 2015 U.S. Dist. LEXIS 35679 at *34 (D.N.J. Mar. 23, 2015). There, this Court found that "Mylan Inc. and Mylan [Pharms.] consented to the Court's jurisdiction by registering to do business in New Jersey, by appointing an in-state agent for service of process in New Jersey, and by actually engaging in a substantial amount of business in this state." *Id.*

231. Similarly, this Court denied Mylan Pharms.' Motion to Dismiss for lack of personal jurisdiction, holding that "Mylan [Pharms.] consented to personal jurisdiction by complying with the State of New Jersey's registration requirements and appointing an in-state agent to accept service of process." *Boehringer Ingelheim Pharma Gmbh & Co. KG, et al. v. Teva Pharm. USA, Inc., et al.*, No. 3:14-cv-07811, D.I. 76 at 4 (D.N.J. July 16, 2015).

232. This Court has personal jurisdiction over Mylan Pharms. by virtue of, among other things, (1) its continuous and systematic contacts with New Jersey; (2) its consent to jurisdiction in New Jersey by its registration to do business in New Jersey and appointment of a registered agent in New Jersey for the receipt of service of process; (3) its registration as a drug manufacturer and wholesaler in New Jersey; (4) its acts of patent infringement under 35 U.S.C. § 271(e)(2) in New Jersey; (5) its sale of a substantial volume of prescription drugs in New Jersey; (6) its purposefully availing itself of the jurisdiction of this court in the past; and (7) its conduct by and through, and in concert with, Mylan Inc.

233. This Court has personal jurisdiction over Mylan Inc. by virtue of, among other things, (1) its consent to jurisdiction in New Jersey by its registration to do business in New Jersey and appointment of registered agent in New Jersey for the receipt of service of process;

(2) its presence in New Jersey, including a subsidiary in Basking Ridge, NJ; (3) its acts of tortious patent infringement that will result in foreseeable harm in New Jersey; (4) its sale of a substantial volume of prescription drugs in New Jersey; (5) its continuous and systematic contacts with New Jersey; (6) its purposefully availing itself of the jurisdiction of this court in the past; and (7) its conduct by and through, and in concert with, Mylan Pharms.

Defendant Par

234. Upon information and belief, Par Pharm. Inc. is in the business of formulating, manufacturing, marketing, and selling generic prescription pharmaceutical drugs that it distributes in New Jersey and throughout the United States.

235. This Court has personal jurisdiction over Par Pharm. Inc. by virtue of the fact that, *inter alia*, it has committed a tortious act of patent infringement under 35 U.S.C. § 271(e)(2), and intends a future course of conduct that includes acts of patent infringement in New Jersey. These acts have led and will lead to foreseeable harm and injury to Janssen, including to Plaintiff Janssen R&D, a New Jersey resident corporation, in New Jersey. For example, upon information and belief, Par Pharm. Inc. is actively preparing to make the proposed generic copies of ZYTIGA® (abiraterone acetate) that are the subject of Par's ANDA No. 208168, and to use, sell, and offer for sale such generic copies in this State and this judicial district.

236. Upon information and belief, Par Pharm. Inc. has substantial, continuous and systematic contacts with New Jersey, including corporate headquarters in Woodcliff Lake, NJ and Sales and Administration offices in Parsippany, NJ,[19] and it has registered to do business in New Jersey and appointed a registered agent for service of process in New Jersey.

19 http://www.parpharm.com/generics/index.php?option=com_content&view=article&id=49&Itemi

237. Upon information and belief, Par Pharm. Inc has previously submitted to the jurisdiction of this Court and has asserted counterclaims in this jurisdiction. *See, e.g. Shire LLC v. Par Pharm., Inc. and Par Pharm. Cos, Inc.*, No. 1:15-cv-01454; *Supernus Pharms., Inc. v. Par Pharm. Cos., Inc. and Par Pharm., Inc.*, No. 2:15-cv-00326*; Par Pharm., Inc. and Alkermes Pharma Ireland Ltd. v. Breckenridge Pharm., Inc.*, No. 1:13-cv-04000; and *MSD Consumer Prods., Inc., et al. v. Par Pharm., Inc.*, No. 3:10-cv-04837.

238. Upon information and belief, Par Pharm. Cos. Inc., directly or through Par Pharm. Inc., is in the business of formulating, manufacturing, marketing, and selling generic prescription pharmaceutical drugs that it distributes in New Jersey and throughout the United States.

239. Upon information and belief, Par Pharm. Cos. Inc. has substantial, continuous and systematic contacts with New Jersey, including corporate headquarters in Woodcliff Lake, NJ and Sales and Administration offices in Parsippany, NJ,[20] and through the direction of the operations and management of Par Pharm. Inc. in New Jersey.

240. Upon information and belief, Par Pharm. Cos. Inc. filed a Form 10-K with the SEC, which states that Par Pharm. Cos. Inc. "principally through its wholly owned operating subsidiary, Par Pharmaceutical, Inc., specializes in developing, licensing, manufacturing,

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d=71(last visited July 30, 2015); http://www.parpharm.com/index.php?option=com_content&view=article&id=77&Itemid=94 (last visited July 30, 2015).

[20] http://www.parpharm.com/generics/index.php?option=com_content&view=article&id=49&Itemid=71 (last visited July 30, 2015); http://www.parpharm.com/index.php?option=com_content&view=article&id=77&Itemid=94 (last visited July 30, 2015).

marketing and distributing generic drugs in the United States." [21] The Form 10-K also states that "[t]he focus of Par Pharmaceutical is to develop, license, manufacture, market and distribute generic prescription drugs . . . ."[22]

241. Upon information and belief, Par Pharm. Cos. Inc. issued a press release stating that "[Par Pharm. Cos. Inc.] is a U.S.-based specialty pharmaceutical company. Through its wholly owned subsidiary's two operating divisions, Par Pharmaceutical and Strativa Pharmaceuticals, it develops, manufactures and markets higher-barrier-to-entry generic drugs and niche, innovative proprietary pharmaceuticals."[23]

242. Upon information and belief, Par Pharm. Cos. Inc. has previously submitted to the jurisdiction of this Court, and has asserted counterclaims in this jurisdiction. *See, e.g., Supernus Pharms., Inc. v. Par Pharm. Cos., Inc. and Par Pharm., Inc.*, No. 2:15-cv-00326.

243. Upon information and belief, Par Pharm. Inc. and Par Pharm. Cos. Inc. hold themselves out as a single entity for the purposes of manufacturing, selling, marketing, distribution, and importation of generic drug products in New Jersey and throughout the United States.

244. On information and belief, Par Pharm. Inc. and Par Pharm. Cos. Inc. are agents of each other with respect to formulating, manufacturing, packaging, marketing and/or selling pharmaceutical products throughout the United States and will do the same with respect to Par's ANDA Product for which they have sought approval from the FDA.

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[21] March 13, 2015 Form 10-K, at 3; http://pr.parpharm.com/phoenix.zhtml?c=81806&p=irol-sec (last visited July 17, 2015).

[22] *Id.* at 4.

[23] "Par Pharmaceutical Completes Acquisition of Anchen," http://pr.parpharm.com/phoenix.zhtml?c=81806&p=irol-newsArticle&ID=1631719 (last visited July 17, 2015).

245. On information and belief, Par Pharm. Inc. and Par Pharm. Cos. Inc. are acting in concert with each other with respect to formulating, manufacturing, packaging, marketing and/or selling pharmaceutical products throughout the United States and will do the same with respect to Par's ANDA Product for which they have sought approval from the FDA.

246. Upon information and belief, Par Pharm. Cos. Inc. together with its affiliate and/or agent, Par Pharm. Inc., filed the Par ANDA with the FDA that is at issue in this patent infringement suit.

247. Upon information and belief, Par Pharm. Cos. Inc. alone and/or together with its affiliate and/or agent Par Pharm. Inc. has committed, or aided, abetted, actively induced, contributed to, or participated in the commission of an act of patent infringement under 35 U.S.C. § 271(e)(2) that has led and/or will lead to foreseeable harm and injury to Janssen, including Janssen R&D, which is a New Jersey company, in New Jersey.

248. This Court has personal jurisdiction over Par Pharm. Inc. by virtue of, among other things, (1) its continuous and systematic contacts with New Jersey, including places of business in Woodcliff Lake, NJ and Parsippany, NJ; (2) its consent to jurisdiction in New Jersey by its registration to do business in New Jersey, and appointment of a registered agent for service of process; (3) its registration as a drug manufacturer and wholesaler in New Jersey; (4) its acts of tortious patent infringement that will result in foreseeable harm in New Jersey; (5) its sale of a substantial volume of prescription drugs in New Jersey; (6) its purposefully availing itself of the jurisdiction of this court in the past; and (7) its conduct by, through, and in concert with, Par Pharm. Cos. Inc.

249. This Court has personal jurisdiction over Par Pharm. Cos. Inc. by virtue of, among other things, (1) its continuous and systematic contacts with New Jersey, including places

of business at Woodcliff Lake, NJ and Parsippany, NJ; (2) its consent to jurisdiction in New Jersey by its registration to do business in New Jersey, and appointment of registered agent to accept service of process; (3) its acts of tortious patent infringement that will result in foreseeable harm in New Jersey; (4) its sale of a substantial volume of prescription drugs in New Jersey; (5) its purposefully availing itself of the jurisdiction of this court in the past; and (6) its conduct by and through, and in concert with, Par Pharm. Inc.

Defendant Sun

250. By email dated July 15, 2015, through its counsel, Sun has stated that "Sun will consent to jurisdiction in the U.S. District Court of New Jersey for any action brought under 21 U.S.C. 355(j)(5)(B)(iii), pertaining to the [Sun Notice Letter] only."

251. Upon information and belief, Sun Ltd., directly and through its wholly-owned subsidiaries, including Sun Inc., is in the business of formulating, manufacturing, marketing, and selling generic prescription pharmaceutical drugs that it distributes in New Jersey and throughout the United States.

252. Upon information and belief, Sun Inc., is the authorized U.S. agent for Sun Ltd.

253. This Court has personal jurisdiction over Sun Ltd. and Sun Inc. by virtue of the fact that, *inter alia*, they have committed a tortious act of patent infringement under 35 U.S.C. § 271(e)(2), and intend a future course of conduct that includes acts of patent infringement in New Jersey. These acts have led and will lead to foreseeable harm and injury to Janssen, including to Plaintiff Janssen R&D, a New Jersey resident corporation, in New Jersey. For example, upon information and belief, Sun Ltd. and Sun Inc. are actively preparing to make the proposed generic copies of ZYTIGA® (abiraterone acetate) that are the subject of Sun's ANDA No.

208440, and to use, sell, and offer for sale such generic copies in this State and this judicial district.

254. Upon information and belief, Sun Ltd. has substantial, continuous and systematic contacts with New Jersey, directly and through its wholly owned subsidiaries, including Sun Inc. Upon information and belief, Sun Ltd.'s website states that Sun has "been present in the US since 1996, working with the country's healthcare system with a focus on generics, branded generics and over-the-counter (OTC) products."[24] Sun Ltd.'s website also states that its "US headquarters are in Cranbury, New Jersey,"[25] and lists an R& D Center in Cranbury, New Jersey,[26] and manufacturing facilities in North Brunswick, New Brunswick, and Cranbury, New Jersey.[27]

255. Upon information and belief, Sun Ltd. has previously submitted to the jurisdiction of this Court and has asserted counterclaims in this jurisdiction. *See, e.g., Otsuka Pharm. Co., Ltd. v. Sun Pharm. Indus., Ltd., et al.*, No. 1:14-cv-04307; *AstraZeneca AB, et al. v. Sun Pharma Global FZE, et al.*, No. 3:10-cv-01017; and *Orion Corp. v. Sun Pharm. Indus., Inc. et al.*, No. 3:07-cv-05436.

256. Upon information and belief, Sun Inc. is in the business of formulating, manufacturing, marketing, and selling generic prescription pharmaceutical drugs that it distributes in New Jersey and throughout the United States, including under the control, and for the direct benefit of Sun Ltd.

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[24] http://www.sunpharma.com/USA (last visited July 20, 2015).

[25] *Id.*

[26] http://www.sunpharma.com/operations/research-and-development (last visited July 20, 2015).

[27] http://www.sunpharma.com/operations/manufacturing (last visited July 20, 2015).

257. Upon information and belief, Sun Inc. has substantial, continuous and systematic contacts with New Jersey, including, *inter alia*, a principal place of business in Cranbury, New Jersey, and it has registered to do business in New Jersey, appointed a registered agent in New Jersey for receipt of service of process, and registered as a drug manufacturer and wholesaler in New Jersey.

258. Upon information and belief, Sun Inc. has previously submitted to the jurisdiction of this Court, and has asserted counterclaims in this jurisdiction. *See, e.g., Otsuka Pharm. Co., Ltd. v. Sun Pharm. Indus. Ltd., et al.*, No. 1:14-cv-04307 and *AstraZeneca AB, et al. v. Sun Pharma Global FZE, et al.*, No. 3:10-cv-01017.

259. Upon information and belief, Sun Ltd. and Sun Inc. hold themselves out as a single entity for the purposes of manufacturing, selling, marketing, distribution, and importation of generic drug products in New Jersey and throughout the United States.

260. On information and belief, Sun Ltd. and Sun Inc. are agents of each other with respect to formulating, manufacturing, packaging, marketing and/or selling pharmaceutical products throughout the United States and will do the same with respect to Sun's ANDA Product for which they have sought approval from the FDA.

261. On information and belief, Sun Ltd. and Sun Inc. are acting in concert with each other with respect to formulating, manufacturing, packaging, marketing and/or selling pharmaceutical products throughout the United States and will do the same with respect to Sun's ANDA Product for which they have sought approval from the FDA.

262. Upon information and belief, Sun Ltd., together with its affiliate and/or agent, Sun Inc., submitted the ANDA with the FDA that is at issue in this patent infringement suit.

263. Upon information and belief, Sun Inc., alone and/or together with its affiliate Sun Ltd. has committed, or aided, abetted, actively induced, contributed to, or participated in the commission of an act of patent infringement under 35 U.S.C. § 271(e)(2) that has led and/or will lead to foreseeable harm and injury to Janssen, including to Plaintiff Janssen R&D, which is a New Jersey company, in New Jersey.

264. This Court has personal jurisdiction over Sun Ltd. by virtue of, among other things, (1) its consent to jurisdiction in New Jersey by its express representation that "Sun will consent to jurisdiction in the U.S. District Court of New Jersey for any action brought under 21 U.S.C. 355(j)(505)(B)(iii), pertaining to the [Sun Notice Letter] only"; (2) its continuous and systematic contacts with New Jersey, including its principal place of business (US headquarters) in Cranbury, New Jersey, and several R&D and manufacturing facilities in New Jersey; (3) its acts of tortious patent infringement that will result in foreseeable harm in New Jersey; (4) its sale of a substantial volume of prescription drugs in New Jersey; (5) its purposefully availing itself of the jurisdiction of this court in the past; and (6) its conduct by, through, and in concert with Sun Inc.

265. In the alternative, this Court has personal jurisdiction over Sun Ltd. because the requirements of Federal Rule of Civil Procedure 4(k)(2)(A) are met.

266. This Court has personal jurisdiction over Sun Inc. by virtue of, among other things, (1) its consent to jurisdiction in New Jersey by its express representation that "Sun will consent to jurisdiction in the U.S. District Court of New Jersey for any action brought under 21 U.S.C. 355(j)(5)(B)(iii), pertaining to the [Sun Notice Letter] only"; (2) its continuous and systematic contacts with New Jersey, including its principal place of business (US headquarters) in Cranbury, New Jersey, and several R&D and manufacturing facilities in New Jersey; (3) its

consent to jurisdiction in New Jersey by its registration to do business in New Jersey and appointment of registered agent in New Jersey for the receipt of service of process; (4) its registration as a drug manufacturer and wholesaler in New Jersey; (5) its tortious acts of patent infringement that will result in foreseeable harm in New Jersey; (6) its sale of a substantial volume of prescription drugs in New Jersey; (7) its purposefully availing itself of the jurisdiction of this court in the past; and (8) its conduct by and through, and in concert with, Sun Ltd.

Defendant Teva

267. By email dated July 22, 2015, through its counsel, Teva stated that "Teva will not contest personal jurisdiction in NJ for purposes of this case only."

268. Upon information and belief, Teva Pharms. USA is in the business of formulating, manufacturing, marketing, and selling generic prescription pharmaceutical drugs that it distributes in New Jersey and throughout the United States.

269. This Court has personal jurisdiction over Teva Pharms. USA by virtue of the fact that, *inter alia*, it has committed a tortious act of patent infringement under 35 U.S.C. § 271(e)(2), and intends a future course of conduct that includes acts of patent infringement in New Jersey. These acts have led and will lead to foreseeable harm and injury to Janssen, including to Plaintiff Janssen R&D, a New Jersey resident corporation, in New Jersey. For example, upon information and belief, Teva Pharms. USA is actively preparing to make the proposed generic copies of ZYTIGA® (abiraterone acetate) that are the subject of Teva's ANDA No. 208432, and to use, sell, and offer for sale such generic copies in this State and this judicial district.

270. Upon information and belief, Teva Pharms. USA employs people throughout New Jersey, including at least the following locations: 8 Gloria Ln, Fairfield, NJ 07004; 208 Passaic Avenue, Fairfield, NJ 07004; and 400 Chestnut Ridge Rd., Woodcliff Lake, NJ 07677.

271. Upon information and belief, Teva Pharms. USA has substantial, continuous and systematic contacts with New Jersey, and it has registered to do business in New Jersey, appointed a registered agent in New Jersey for receipt of service of process, and registered as a drug manufacturer and wholesaler in New Jersey.

272. Upon information and belief, Teva Pharms. USA has previously actively litigated in this jurisdiction, submitted to the jurisdiction of this Court and has asserted counterclaims in this jurisdiction. *See, e.g., Teva Pharms. USA, Inc. et al. v. Synthon Pharms., Inc. et al.*, No. 2:15-cv-00472; *Teva Pharms. USA, Inc. et al. v. Dr. Reddy's Labs. Ltd., and Dr. Reddy's Labs. Inc.*, No. 2:15-cv-00471; *Teva Pharms. USA, Inc. et al. v. Dr. Reddy's Labs. Ltd. et al.*, No. 2:14-cv-05672; *Otsuka Pharm. Co., Ltd. v. Teva Pharms.USA, Inc.*, No. 1:14-cv-05878; and *United Therapeutics Corp. v. Teva Pharms. USA, Inc.*, No. 3:14-cv-05498.

273. Upon information and belief, Teva Pharms. Indus. Ltd., directly or through Teva Pharms. USA, is in the business of formulating, manufacturing, marketing, and selling generic prescription pharmaceutical drugs that it distributes in New Jersey and throughout the United States.

274. Upon information and belief, Teva Pharms. Indus. Ltd. has substantial, continuous and systematic contacts with New Jersey, including, but not limited to, the direction of the operations and management of Teva Pharms. USA.

275. Upon information and belief, Teva Pharms. Indus. Ltd. has previously actively litigated in this jurisdiction, submitted to the jurisdiction of this court, and asserted counterclaims

in this jurisdiction. *See e.g.*, *Teva Pharms. USA, Inc. et al. v. Synthon Pharms., Inc. et al.*, No. 2:15-cv-00472; *Teva Pharms. USA, Inc. et al. v. Dr. Reddy's Labs. Ltd., and Dr. Reddy's Labs. Inc.*, No. 2:15-cv-00471; *Teva Pharms. USA, Inc. et al. v. Dr. Reddy's Labs. Ltd. et al.*, No. 2:14-cv-05672; *Helsinn Healthcare S.A., et al. v. Dr. Reddy's Labs. Ltd., et al.*, No. 3:11-3962.

276. Upon information and belief, Teva Pharms. USA and Teva Pharms. Indus. Ltd. hold themselves out as a single entity for the purposes of manufacturing, selling, marketing, distribution, and importation of generic drug products in New Jersey and throughout the United States.

277. On information and belief, Teva Pharms. USA and Teva Pharms. Indus. Ltd. are agents of each other with respect to formulating, manufacturing, packaging, marketing and/or selling pharmaceutical products throughout the United States and will do the same with respect to Teva's ANDA Product for which they have sought approval from the FDA.

278. On information and belief, Teva Pharms. Indus. Ltd. and Teva Pharms. USA are acting in concert with each other with respect to formulating, manufacturing, packaging, marketing and/or selling pharmaceutical products throughout the United States and will do the same with respect to Teva's ANDA Product for which they have sought approval from the FDA.

279. Upon information and belief, Teva Pharms. Indus. Ltd., together with its affiliate and/or agent, Teva Pharms. USA, filed the Teva ANDA with the FDA that is at issue in this patent infringement suit.

280. Upon information and belief, Teva Pharms. Indus. Ltd. alone and/or together with its affiliate and/or agent Teva Pharms. USA has committed, or aided, abetted, actively induced, contributed to, or participated in the commission of an act of patent infringement under 35

U.S.C. § 271(e)(2) that has led and/or will lead to foreseeable harm and injury to Janssen, including to Janssen R&D, which is a New Jersey company, in New Jersey.

281. This Court has personal jurisdiction over Teva Pharms. USA by virtue of, among other things, (1) its consent to jurisdiction in New Jersey by its express representation that it "will not contest personal jurisdiction in NJ for purposes of this case only"; (2) its continuous and systematic contacts with New Jersey, including its facilities in Fairfield, New Jersey and Woodcliff Lake, New Jersey; (3) its consent to jurisdiction in New Jersey by its registration to do business in New Jersey and appointment of registered agent in New Jersey for the receipt of service of process; (4) its registration as a drug manufacturer and wholesaler in New Jersey; (5) its tortious acts of patent infringement that will result in foreseeable harm in New Jersey; (6) its sale of a substantial volume of prescription drugs in New Jersey; (7) its purposefully availing itself of the jurisdiction of this court in the past; and (8) its conduct by and through, and in concert with, Teva Ltd.

282. This Court has personal jurisdiction over Teva Ltd. by virtue of, among other things, (1) its consent to jurisdiction in New Jersey by its express representation that it "will not contest personal jurisdiction in NJ for purposes of this case only"; (2) its continuous and systematic contacts with New Jersey; (3) its acts of tortious patent infringement that will result in foreseeable harm in New Jersey; (4) its sale of a substantial volume of prescription drugs in New Jersey; (5) its purposefully availing itself of the jurisdiction of this court in the past; and (6) its conduct by and through, and in concert with, Teva Pharms. USA.

283. In the alternative, this Court has personal jurisdiction over Teva Ltd. because the requirements of Federal Rule of Civil Procedure 4(k)(2)(A) are met.

Defendant West-Ward

284. Upon information and belief, West-Ward Pharm. is in the business of formulating, manufacturing, marketing, and selling generic prescription pharmaceutical drugs that it distributes in New Jersey and throughout the United States.

285. This Court has personal jurisdiction over West-Ward Pharm. and Hikma Pharms. by virtue of the fact that, *inter alia*, they have committed a tortious act of patent infringement under 35 U.S.C. § 271(e)(2), and intend a future course of conduct that includes acts of patent infringement in New Jersey. These acts have led and will lead to foreseeable harm and injury to Janssen, including to Plaintiff Janssen R&D, a New Jersey resident corporation, in New Jersey. For example, upon information and belief, West-Ward Pharm. and Hikma Pharm. are actively preparing to make the proposed generic copies of ZYTIGA® (abiraterone acetate) that are the subject of Hikma/Westward's ANDA No. 208339, and to use, sell, and offer for sale such generic copies in this State and this judicial district.

286. Upon information and belief, West-Ward Pharm. has substantial, continuous and systematic contacts with New Jersey, including, *inter alia*, a principal place of business in Eatontown, New Jersey, and it has a manufacturing facility in Cherry Hill, New Jersey, is registered to do business in New Jersey and has appointed a registered agent in New Jersey for receipt of service of process, and is registered as a drug wholesaler in New Jersey.

287. Upon information and belief, West-Ward Pharm. has previously actively litigated in this jurisdiction, submitted to jurisdiction of this court, and asserted counterclaims in this jurisdiction. *See, e.g., West-Ward Pharm. Corp. v. Sandoz Inc. and American Regent, Inc.*, No. 3:13-cv-01581; *GlaxoSmithKline plc, et. al. v. Hikma Pharm. Co., Ltd. and West-Ward Pharm. Corp.*, No. 3:12-cv-01965.

288. West-Ward Pharm.'s website states the following: "West-Ward Pharmaceuticals is one of the top 20 generic prescription medication providers in the US, offering both oral solid and injectable pharmaceuticals to a growing number of chain stores, wholesalers, distributors, health systems and government agencies. We are the US agent and subsidiary of Hikma PLC."[28]

289. Upon information and belief, Hikma Pharms. PLC, directly or through its wholly-owned subsidiary West-Ward Pharm., is in the business of formulating, manufacturing, marketing, and selling generic prescription pharmaceutical drugs that it distributes in New Jersey and throughout the United States.

290. Upon information and belief, Hikma Pharms. PLC has substantial, continuous and systematic contacts with New Jersey, including, *inter alia* the direction of operations and management of West-Ward Pharm. Hikma Pharms. PLC's website states that its generic business in the United States "operates as West-Ward Pharmaceuticals, a domestic marketer and manufacturer of generic pharmaceutical products."[29]

291. Upon information and belief, Hikma Pharms. LLC, directly or through its wholly-owned subsidiary West-Ward Pharm., is in the business of formulating, manufacturing, marketing, and selling generic prescription pharmaceutical drugs that it distributes in New Jersey and throughout the United States.

292. Upon information and belief, Hikma Pharms. LLC has substantial, continuous and systematic contacts with New Jersey, including, *inter alia* the direction of operations and management of West-Ward Pharm.

[28] http://www.west-ward.com/en/AboutUs.aspx (last visited July 23, 2015).

[29] http://www.hikma.com/en/about-hikma/our-businesses.aspx (last visited July 23, 2015).

293. Upon information and belief, Hikma Pharms. LLC has previously submitted to the jurisdiction of this Court and has asserted counterclaims in this jurisdiction. *See, e.g. Glaxo Group Ltd. and SmithKline Beecham Corp. v. West-Ward Pharms. Inc. and Hikma Pharms.*, No. 2:03-cv-04791.

294. Upon information and belief, Arab Pharm. Manuf. Co., directly or through its parents and/or affiliates West-Ward Pharm., Hikma PLC, Hikma LLC, is in the business of formulating, manufacturing, marketing, and selling generic prescription pharmaceutical drugs that it distributes in New Jersey and throughout the United States.

295. Upon information and belief, West-Ward Pharm., Arab Pharm. Manuf. Co., Hikma Pharms. PLC, and Hikma Pharms. LLC hold themselves out as a single entity for the purposes of manufacturing, selling, marketing, distribution, and importation of generic drug products in New Jersey and throughout the United States.

296. On information and belief, West-Ward Pharm., Arab Pharm. Manuf. Co., Hikma Pharms. PLC, and Hikma Pharms. LLC are agents of each other with respect to formulating, manufacturing, packaging, marketing and/or selling pharmaceutical products throughout the United States and will do the same with respect to West-Ward's ANDA Product for which they have sought approval from the FDA.

297. On information and belief, West-Ward Pharm., Arab Pharm. Manuf. Co., Hikma Pharms. PLC, and Hikma Pharms. LLC are acting in concert with each other with respect to formulating, manufacturing, packaging, marketing and/or selling pharmaceutical products throughout the United States and will do the same with respect to Hikma/West-Ward's ANDA Product for which Hikma/West-Ward has sought approval from the FDA.

298. Upon information and belief, Hikma Pharms. together with its affiliate and/or agent, West-Ward Pharm., filed the Hikma/West-Ward ANDA with the FDA that is at issue in this patent infringement suit.

299. Upon information and belief, West-Ward Pharms. and/or Arab Pharm. Manuf. Co. alone and/or together with their affiliate and agent Hikma Pharms. have committed, or aided, abetted, actively induced, contributed to, or participated in the commission of an act of patent infringement under 35 U.S.C. § 271(e)(2) that has led and/or will lead to foreseeable harm and injury to Janssen, including to Janssen R&D, which is a New Jersey company, in New Jersey.

300. This Court has personal jurisdiction over West-Ward Pharm. by virtue of, among other things, (1) its continuous and systematic contacts with New Jersey, including its principal place of business in Eatontown, NJ and a manufacturing facility in Cherry Hill, NJ; (2) its consent to jurisdiction in New Jersey by its registration to do business in New Jersey and appointment of registered agent in New Jersey for the receipt of service of process; (3) its registration as a drug manufacturer and wholesaler in New Jersey; (4) its acts of tortious patent infringement that will result in foreseeable harm in New Jersey; (5) its sale of a substantial volume of prescription drugs in New Jersey; (6) its purposefully availing itself of the jurisdiction of this court in the past; and (7) its conduct by, through, and in concert with, Hikma Pharms. PLC Hikma Pharms. LLC., and Arab Pharm. Manuf. Co.

301. This Court has personal jurisdiction over Hikma Pharms. PLC by virtue of, among other things, (1) its continuous and systematic contacts with New Jersey; (2) its tortious acts of patent infringement that will result in foreseeable harm in New Jersey; (3) its sale of a substantial volume of prescription drugs in New Jersey, either directly or through its wholly-

owned subsidiary, West-Ward Pharm.; and (4) its conduct by and through, and in concert with West-Ward Pharm., Hikma Pharms. LLC., and Arab Pharm. Manuf. Co.

302. This Court has personal jurisdiction over Hikma Pharms. LLC by virtue of, among other things, (1) its continuous and systematic contacts with New Jersey; (2) its tortious acts of patent infringement that will result in foreseeable harm in New Jersey; (3) its sale of a substantial volume of prescription drugs in New Jersey, either directly or through West-Ward Pharm.; (4) its purposefully availing itself of the jurisdiction of this court in the past; and (5) its conduct by and through, and in concert with, West-Ward Pharm., Hikma Pharm. PLC., and Arab Pharm. Manuf. Co.

303. This Court has personal jurisdiction over Arab Pharm. Manuf. Co. by virtue of, among other things, (1) its continuous and systematic contacts with New Jersey; (2) its acts of tortious patent infringement that will result in foreseeable harm in New Jersey; (3) its sale of a substantial volume of prescription drugs in New Jersey, either directly or through West-Ward Pharm.; and (4) its conduct by, through, and in concert with, West-Ward Pharm., Hikma Pharms. PLC and Hikma Pharms. LLC.

304. In the alternative, this Court has personal jurisdiction over Hikma Pharms. PLC, Hikma Pharms. LLC, and Arab Pharm. Manuf. Co. because the requirements of Federal Rule of Civil Procedure 4(k)(2)(A) are met.

Defendant Wockhardt

305. By email dated July 16, 2015, through its counsel, Wockhardt stated that "Wockhardt ... will not contest jurisdiction in New Jersey only for the action that Janssen intends to pursue with respect to Wockhardt's ANDA reference Zytiga."

306. Upon information and belief, Wockhardt Bio, directly or through Wockhardt USA, is in the business of formulating, manufacturing, marketing, and selling generic prescription pharmaceutical drugs throughout the United States, including New Jersey.

307. Upon information and belief, Wockhardt USA is the authorized US agent for Wockhardt Bio.

308. This Court has personal jurisdiction over Wockhardt Bio and/or Wockhardt USA by virtue of the fact that, *inter alia*, it has committed a tortious act of patent infringement under 35 U.S.C. § 271(e)(2), and intend a future course of conduct that includes acts of patent infringement in New Jersey. These acts have led and will lead to foreseeable harm and injury to Janssen, including Plaintiff Janssen R&D, a New Jersey resident corporation, in New Jersey. For example, upon information and belief, Wockhardt Bio and/or Wockhardt USA are actively preparing to make the proposed generic copies of ZYTIGA® (abiraterone acetate) that are the subject of Wockhardt's ANDA No. 208380, and to use, sell, and offer for sale such generic copies in this State and this judicial district.

309. Upon information and belief, Wockhardt Bio has substantial, continuous and systematic contacts with New Jersey, directly or through its wholly owned subsidiary, Wockhardt USA.

310. Upon information and belief, Wockhardt Bio has previously submitted to the jurisdiction of this Court and has asserted counterclaims in this jurisdiction. *See, e.g., Takeda Pharm. Co. Ltd., et al. v. Wockhardt Bio AG, et al.*, No. 3:13-cv-06427.

311. Upon information and belief, Wockhardt USA is in the business of formulating, manufacturing, marketing, and selling generic prescription pharmaceutical drugs that it distributes in New Jersey and throughout the United States.

312. Upon information and belief, Wockhardt USA has substantial, continuous and systematic contacts with New Jersey, including, *inter alia*, a principal place of business in Parsippany, New Jersey, and it has registered to do business in New Jersey, appointed a registered agent in New Jersey for receipt of service of process, and is registered as a drug wholesaler in New Jersey.

313. Wockhardt USA has previously submitted to the jurisdiction of this Court and has asserted counterclaims in this jurisdiction. *See, e.g., Takeda Pharm. Co. Ltd., et al. v. Wockhardt Bio AG, et al.*, No. 3:13-cv-06427.

314. Upon information and belief, Wockhardt Ltd., directly or through Wockhardt USA, is in the business of formulating, manufacturing, marketing, and selling generic prescription pharmaceutical drugs throughout the United States, including New Jersey.

315. Upon information and belief, Wockhardt Ltd. has substantial, continuous and systematic contacts with New Jersey, directly or through Wockhardt Bio and/or Wockhardt USA.

316. Upon information and belief, Wockhardt Ltd. has previously submitted to the jurisdiction of this Court, and has asserted counterclaims in this jurisdiction. *See, e.g., Takeda Pharm. Co. Ltd., et al. v. Wockhardt Bio AG, et al.*, No. 3:13-cv-06427.

317. Upon information and belief, Wockhardt Bio, Wockhardt Ltd., and Wockhardt USA hold themselves out as a single entity for the purposes of manufacturing, selling, marketing, distribution, and importation of generic drug products in New Jersey and throughout the United States.

318. On information and belief, Wockhardt Bio, Wockhardt Ltd., and Wockhardt USA are agents of each other with respect to formulating, manufacturing, packaging, marketing and/or

selling pharmaceutical products throughout the United States and will do the same with respect to Wockhardt's ANDA Product for which they have sought approval from the FDA.

319. On information and belief, Wockhardt Bio, Wockhardt Ltd., and Wockhardt USA are acting in concert with each other with respect to formulating, manufacturing, packaging, marketing and/or selling pharmaceutical products throughout the United States and will do the same with respect to Wockhardt's ANDA Product for which they have sought approval from the FDA.

320. Upon information and belief, Wockhardt Bio alone and/or together with Wockhardt USA and/or Wockhardt Ltd., filed the Wockhardt ANDA with the FDA that is at issue in this patent infringement suit.

321. Upon information and belief, Wockhardt USA and/or Wockhardt Ltd., alone and/or together with Wockhardt Bio, have committed, or aided, abetted, actively induced, contributed to, or participated in the commission of an act of patent infringement under 35 U.S.C. § 271(e)(2) that has led and/or will lead to foreseeable harm and injury to Janssen, including to Janssen R&D, which is a New Jersey company, in New Jersey.

322. This Court has personal jurisdiction over Wockhardt Bio by virtue of, among other things, (1) its consent to jurisdiction by its express representation that "Wockhardt ...will not contest jurisdiction in New Jersey only for the action that Janssen intends to pursue with respect to Wockhardt's ANDA referencing Zytiga"; (2) its continuous and systematic contacts with New Jersey; (3) its acts of tortious patent infringement that will result in foreseeable harm in New Jersey; (4) its sale of a substantial volume of prescription drugs in New Jersey; (5) its purposefully availing itself of the jurisdiction of this court in the past; and (6) its conduct by and through, and in concert with, Wockhardt USA and Wockhardt Ltd.

323. This Court has personal jurisdiction over Wockhardt USA by virtue of, among other things, (1) its continuous and systematic contacts with New Jersey, including its principal place of business in Parsippany, New Jersey; (2) its consent to jurisdiction in New Jersey by its registration to do business in New Jersey and appointment of registered agent in New Jersey for the receipt of service of process; (3) its registration with the State of New Jersey's Department of Health as a drug Wholesaler; (4) its tortious acts of patent infringement that will result in foreseeable harm in New Jersey; (5) its sale of a substantial volume of prescription drugs in New Jersey; (6) its purposefully availing itself of the jurisdiction of this court in the past; and (7) its conduct by and through, and in concert with, Wockhardt Bio and Wockhardt Ltd.

324. This Court has personal jurisdiction over Wockhardt Ltd by virtue of, among other things, (1) its sale of a substantial volume of prescription drugs in New Jersey; (2) its continuous and systematic contacts with New Jersey; (3) its purposefully availing itself of the jurisdiction of this court in the past; and (4) its conduct by and through, and in concert with, Wockhardt Bio and Wockhardt USA.

325. In the alternative, this Court has personal jurisdiction over Wockhardt Ltd. and Wockhardt Bio AG because the requirements of Federal Rule of Civil Procedure 4(k)(2)(A) are met.

Defendant Hetero

326. By email dated September 18, 2015, Hetero has stated that "Hetero USA Inc., Hetero Labs Ltd. Unit V, and Hetero Labs Ltd. (collectively "Hetero") consents to personal jurisdiction in the U.S. District Court of New Jersey for purposes of any action relating to Hetero's ANDA # 208349 directed to Abiraterone Acetate (ZYTIGA)."

327. Upon information and belief, Hetero USA is in the business of formulating, manufacturing, marketing, and selling generic prescription pharmaceutical drugs that it distributes in New Jersey and throughout the United States.

328. This Court has personal jurisdiction over Hetero USA, Hetero Unit-V, and Hetero Ltd. by virtue of the fact that, *inter alia*, they have committed a tortious act of patent infringement under 35 U.S.C. § 271(e)(2), and intend a future course of conduct that includes acts of patent infringement in New Jersey. These acts have led and will lead to foreseeable harm and injury to Plaintiffs, including to Plaintiff Janssen R&D, a New Jersey resident corporation, in New Jersey. For example, upon information and belief, Hetero USA, Hetero Unit-V, and Hetero Ltd. are actively preparing to make the proposed generic copies of ZYTIGA® (abiraterone acetate) that are the subject of Hetero's ANDA No. 208349, and to use, sell, and offer for sale such generic copies in this State and this judicial district.

329. Upon information and belief, Hetero USA has substantial, continuous and systematic contacts with New Jersey, including, *inter alia*, having a principal place of business in Piscataway, New Jersey.

330. Upon information and belief, Hetero USA has previously submitted to the jurisdiction of this Court and asserted counterclaims in this jurisdiction. *See, e.g., Takeda Gmbh, et al. v. Hetero USA, Inc. et al.*, No. 3:15-cv-03385; *Otsuka Pharm. Co., Ltd. v. Hetero Drugs Ltd., et al.*, No. 1:15-cv-00161; and *Janssen Prods., L.P., et al. v. Hetero Labs. Ltd. et al.*, No. 2:13-cv-01444.

331. Upon information and belief, Hetero Unit-V, either directly or through Hetero USA and/or Hetero Ltd., is in the business of formulating, manufacturing, marketing, and selling generic prescription pharmaceutical drugs in New Jersey and throughout the United States.

332. Upon information and belief, Hetero Unit-V has substantial, continuous and systematic contacts with New Jersey, including, *inter alia*, the direction of operations and management of Hetero USA.

333. Upon information and belief, Hetero Ltd., directly or through Hetero USA and/or Hetero Unit-V, is in the business of formulating, manufacturing, marketing, and selling generic prescription pharmaceutical drugs in New Jersey and throughout the United States.

334. Upon information and belief, Hetero Ltd. has substantial, continuous and systematic contacts with New Jersey, including, *inter alia*, the direction of operations and management of Hetero USA and/or Hetero Unit-V.

335. Upon information and belief, Hetero Ltd. has previously submitted to the jurisdiction of this Court and asserted counterclaims in this jurisdiction. *See, e.g., Takeda Gmbh, et al. v. Hetero USA, Inc. et al.*, No. 3:15-cv-03385; *Otsuka Pharm. Co., Ltd. v. Hetero Drugs Ltd., et al.*, No. 1:15-cv-00161; and *Janssen Prods., L.P. and Janssen R&D Ireland v. Hetero Labs. Ltd. et al.*, No. 2:13-cv-01444.

336. Upon information and belief, Hetero USA, Hetero Unit-V, and Hetero Ltd. hold themselves out as a single entity for the purposes of manufacturing, selling, marketing, distribution, and importation of generic drug products in New Jersey and throughout the United States. Hetero's website states that "[t]he company's vertical integration in process research and chemistry, API manufacturing, formulation development, manufacturing and commercialization have enabled our pharmaceutical partners and global healthcare markets to receive medicines more rapidly and across wider populations of people in need."[30] Hetero's website further states

[30] *See* http://heteroworld.com/pages/business-overview/ (last visited Sept. 2, 2015).

that "Hetero's full vertical integration of products and services ensure the most cost-competitive supply of pharmaceutical APIs and finished dosage products."[31]

337. Upon information and belief, Hetero USA, Hetero Unit-V, and Hetero Ltd. are agents of each other with respect to formulating, manufacturing, packaging, marketing and/or selling pharmaceutical products throughout the United States and will do the same with respect to Hetero's ANDA Product for which they have sought approval from the FDA.

338. Upon information and belief, Hetero USA, Hetero Unit-V, and Hetero Ltd. are acting in concert with each other with respect to formulating, manufacturing, packaging, marketing and/or selling pharmaceutical products throughout the United States and will do the same with respect to Hetero's ANDA Product for which they have sought approval from the FDA.

339. Upon information and belief, Hetero Unit-V and Hetero Ltd., together with their affiliate and/or agent, Hetero USA, filed the Hetero ANDA with the FDA that is at issue in this patent infringement suit.

340. Upon information and belief, Hetero Unit-V and Hetero Ltd., alone and/or together with their affiliate and/or agent Hetero USA, have committed, or aided, abetted, actively induced, contributed to, or participated in the commission of an act of patent infringement under 35 U.S.C. § 271(e)(2) that has led and/or will lead to foreseeable harm and injury to Plaintiffs, including to Janssen R&D, which is a New Jersey company, in New Jersey.

341. This Court has personal jurisdiction over Hetero USA by virtue of, among other things, (1) its consent to jurisdiction in New Jersey by its express representation that "Hetero USA Inc., Hetero Labs Ltd. Unit V, and Hetero Labs Ltd. (collectively "Hetero") consents to

[31] *See* http://heteroworld.com/pages/why-hetero/ (last visited Sept. 2, 2015).

personal jurisdiction in the U.S. District Court of New Jersey for purposes of any action relating to Hetero's ANDA # 208349 directed to Abiraterone Acetate (ZYTIGA)"; (2) its continuous and systematic contacts with New Jersey, including its principal place of business in Piscataway, New Jersey; (3) its consent to jurisdiction in New Jersey by its registration to do business in New Jersey and appointment of a registered agent in New Jersey for the receipt of service of process; (4) its registration as a drug wholesaler in New Jersey; (5) its tortious acts of patent infringement that will result in foreseeable harm in New Jersey; (6) its sale of a substantial volume of prescription drugs in New Jersey; (7) its purposefully availing itself of the jurisdiction of this Court in the past; and (8) its conduct by, through, and in concert with Hetero Unit-V and Hetero Ltd.

342. This Court has personal jurisdiction over Hetero Unit-V by virtue of, among other things, (1) its consent to jurisdiction in New Jersey by its express representation that "Hetero USA Inc., Hetero Labs Ltd. Unit V, and Hetero Labs Ltd. (collectively "Hetero") consents to personal jurisdiction in the U.S. District Court of New Jersey for purposes of any action relating to Hetero's ANDA # 208349 directed to Abiraterone Acetate (ZYTIGA)"; (2) its continuous and systematic contacts with New Jersey; (3) its tortious acts of patent infringement that will result in foreseeable harm in New Jersey; (4) its sale of a substantial volume of prescription drugs in New Jersey; and (5) its conduct by, through, and in concert with Hetero USA and Hetero Ltd.

343. This Court has personal jurisdiction over Hetero Ltd. by virtue of, among other things, (1) its consent to jurisdiction in New Jersey by its express representation that "Hetero USA Inc., Hetero Labs Ltd. Unit V, and Hetero Labs Ltd. (collectively "Hetero") consents to personal jurisdiction in the U.S. District Court of New Jersey for purposes of any action relating to Hetero's ANDA # 208349 directed to Abiraterone Acetate (ZYTIGA)"; (2) its continuous and

systematic contacts with New Jersey; (3) its tortious acts of patent infringement that will result in foreseeable harm in New Jersey; (4) its sale of a substantial volume of prescription drugs in New Jersey; (5) its purposefully availing itself of the jurisdiction of this court in the past; and (6) its conduct by, through, and in concert with Hetero USA and Hetero Unit-V.

344. In the alternative, this Court has personal jurisdiction over Hetero Unit-V and Hetero Ltd. because the requirements of Federal Rule of Civil Procedure 4(k)(2)(A) are met.

COUNT I: INFRINGEMENT OF THE '213 PATENT BY ACTAVIS

345. Plaintiffs incorporate the preceding paragraphs as if fully set forth herein.

346. The use of Actavis's ANDA Product is covered by one or more claims of the '213 patent.

347. The submission of Actavis's ANDA No. 208274 with a Paragraph IV certification regarding the '213 patent for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Actavis's ANDA Product before the expiration of the '213 patent constitutes infringement of one or more of the claims of the '213 patent under 35 U.S.C. § 271(e)(2).

348. The commercial manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Actavis's ANDA Product before the expiration of the '213 patent would infringe one or more claims of the '213 patent under 35 U.S.C. § 271.

349. The use of Actavis's ANDA Product in accordance with and as directed by Actavis's proposed labeling for that product before the expiration of the '213 patent would infringe one or more claims of the '213 patent under 35 U.S.C. § 271.

350. Unless enjoined by this Court, Actavis intends to, and will, engage in the manufacture, use, offer for sale, sale, marketing, distributing, and/or importation of Actavis's ANDA Product immediately and imminently upon approval of the Actavis ANDA.

351. Unless enjoined by this Court, Actavis intends to, and will, actively induce infringement of the '213 patent when the Actavis ANDA is approved, and intends to, and will do so, immediately and imminently upon approval.

352. Actavis knows that Actavis's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '213 patent, and that Actavis's ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. Unless enjoined by this Court, Actavis intends to, and will, contribute to the infringement of the '213 patent immediately and imminently upon approval of the Actavis ANDA.

353. The foregoing actions by Actavis prior to the expiration of the '213 patent constitute and/or will constitute infringement, active inducement of infringement, and/or contribution to the infringement by others under 35 U.S.C. §§ 271(a), (b) and/or (c).

354. Actavis had knowledge of the '213 patent and is knowingly and willfully infringing the '213 patent.

355. Actavis acted without a reasonable basis for believing that it would not be liable for infringing the '213 patent, actively inducing infringement of the '213 patent, and/or contributing to the infringement by others of the '213 patent.

356. Unless Actavis is enjoined from infringing the '213 patent, actively inducing infringement of the '213 patent, and/or contributing to the infringement of the '213 patent, Plaintiffs will suffer irreparable injury for which they have no adequate remedy at law. Pursuant

to 35 U.S.C. § 271(e)(4)(B) and 283 and Rule 65, Fed. R. Civ. P., a preliminary and permanent injunction should be entered preventing further infringement.

357. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court that the FDA set the effective date of approval for Actavis's ANDA No. 208274 to be a date which is not earlier than the expiration date on which the '213 patent expires or any later expiration of exclusivity to which Plaintiffs are or become entitled.

358. This case is "exceptional," as that term is used in 35 U.S.C. § 285.

COUNT II: INFRINGEMENT OF THE '438 PATENT BY ACTAVIS

359. Plaintiffs incorporate the preceding paragraphs as if fully set forth herein.

360. The use of Actavis's ANDA Product is covered by one or more claims of the '438 patent.

361. The submission of Actavis's ANDA No. 208274 with a Paragraph IV certification regarding the '438 patent for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Actavis's ANDA Product before the expiration of the '438 patent constitutes infringement of one or more of the claims of the '438 patent under 35 U.S.C. § 271(e)(2).

362. The commercial manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Actavis's ANDA Product before the expiration of the '438 patent would infringe one or more claims of the '438 patent under 35 U.S.C. § 271.

363. The use of Actavis's ANDA Product in accordance with and as directed by Actavis's proposed labeling for that product before the expiration of the '438 patent would infringe one or more claims of the '438 patent under 35 U.S.C. § 271.

364. Unless enjoined by this Court, Actavis intends to, and will, engage in the manufacture, use, offer for sale, sale, marketing, distributing, and/or importation of Actavis's ANDA Product immediately and imminently upon approval of the Actavis ANDA.

365. Unless enjoined by this Court, Actavis intends to, and will, actively induce infringement of the '438 patent when the Actavis ANDA is approved, and intends to, and will do so, immediately and imminently upon approval.

366. Actavis knows that Actavis's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '438 patent, and that Actavis's ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. Unless enjoined by this Court, Actavis intends to, and will, contribute to the infringement of the '438 patent immediately and imminently upon approval of the Actavis ANDA.

367. The foregoing actions by Actavis prior to the expiration of the '438 patent constitute and/or will constitute infringement, active inducement of infringement, and/or contribution to the infringement by others under 35 U.S.C. §§ 271(a), (b) and/or (c).

368. Actavis had knowledge of the '438 patent and is knowingly and willfully infringing the '438 patent.

369. Actavis acted without a reasonable basis for believing that it would not be liable for infringing the '438 patent, actively inducing infringement of the '438 patent, and/or contributing to the infringement by others of the '438 patent.

370. Unless Actavis is enjoined from infringing the '438 patent, actively inducing infringement of the '438 patent, and/or contributing to the infringement of the '438 patent, Plaintiffs will suffer irreparable injury for which they have no adequate remedy at law. Pursuant

to 35 U.S.C. § 271(e)(4)(B) and 283 and Rule 65, Fed. R. Civ. P., a preliminary and permanent injunction should be entered preventing further infringement.

371. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court that the FDA set the effective date of approval for Actavis's ANDA No. 208274 to be a date which is not earlier than the date on which the '438 patent expires or any later expiration of exclusivity to which Plaintiffs are or become entitled.

372. This case is "exceptional," as that term is used in 35 U.S.C. § 285.

COUNT III: INFRINGEMENT OF THE '438 PATENT BY AMNEAL

373. Janssen incorporates the preceding paragraphs as if fully set forth herein.

374. The use of Amneal's ANDA Product is covered by one or more claims of the '438 patent.

375. The submission of Amneal's ANDA No. 208327 with a Paragraph IV certification regarding the '438 patent for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Amneal's ANDA Product before the expiration of the '438 patent constitutes infringement of one or more of the claims of the '438 patent under 35 U.S.C. § 271(e)(2).

376. The commercial manufacture, use, offer for sale, sale, marketing, distributing, and/or importation of Amneal's ANDA Product before the expiration of the '438 patent would infringe one or more claims of the '438 patent under 35 U.S.C. § 271.

377. The use of Amneal's ANDA Product in accordance with and as directed by Amneal's proposed labeling for that product before the expiration of the '438 patent would infringe one or more claims of the '438 patent under 35 U.S.C. § 271.

378. Unless enjoined by this Court, Amneal intends to, and will, engage in the manufacture, use, offer for sale, sale, marketing, distributing, and/or importation of Amneal's ANDA Product immediately and imminently upon approval of the Amneal ANDA.

379. Unless enjoined by this Court, Amneal intends to, and will, actively induce infringement of the '438 patent when the Amneal ANDA is approved, and intends to, and will, do so immediately and imminently upon approval.

380. Amneal knows that Amneal's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '438 patent, and that Amneal's ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. Unless enjoined by this Court, Amneal intends to, and will, contribute to the infringement of the '438 patent immediately and imminently upon approval of the Amneal ANDA.

381. The foregoing actions by Amneal prior to the expiration of the '438 patent constitute and/or will constitute infringement, active inducement of infringement, and/or contribution to the infringement by others under 35 U.S.C. §§ 271(a), (b) and/or (c).

382. Amneal had knowledge of the '438 patent and is knowingly and willfully infringing the '438 patent.

383. Amneal acted without a reasonable basis for believing that it would not be liable for infringing the '438 patent, actively inducing infringement of the '438 patent, and/or contributing to the infringement by others of the '438 patent.

384. Unless Amneal is enjoined from infringing the '438 patent, actively inducing infringement of the '438 patent, and/or contributing to the infringement of the '438 patent, Janssen will suffer irreparable injury for which Janssen has no adequate remedy at law. Pursuant

to 35 U.S.C. § 271(e)(4)(B) and 283 and Rule 65, Fed. R. Civ. P., a preliminary and permanent injunction should be entered preventing further infringement.

385. Janssen is entitled to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court that the FDA set the effective date of approval for Amneal's ANDA No. 208327 to be a date which is not earlier than the date on which the '438 patent expires or any later expiration of exclusivity to which Janssen is or becomes entitled.

386. This case is "exceptional," as that term is used in 35 U.S.C. § 285.

COUNT IV: INFRINGEMENT OF THE '438 PATENT BY APOTEX

387. Janssen incorporates the preceding paragraphs as if fully set forth herein.

388. The use of Apotex's ANDA Product is covered by one or more claims of the '438 patent.

389. The submission of Apotex's ANDA No. 208453 with a Paragraph IV certification regarding the '438 patent for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Apotex's ANDA Product before the expiration of the '438 patent constitutes infringement of one or more of the claims of the '438 patent under 35 U.S.C. § 271(e)(2).

390. The commercial manufacture, use, offer for sale, sale, marketing, distributing, and/or importation of Apotex's ANDA Product before the expiration of the '438 patent would infringe one or more claims of the '438 patent under 35 U.S.C. § 271.

391. The use of Apotex's ANDA Product in accordance with and as directed by Apotex's proposed labeling for that product before the expiration of the '438 patent would infringe one or more claims of the '438 patent under 35 U.S.C. § 271.

392. Unless enjoined by this Court, Apotex intends to, and will, engage in the manufacture, use, offer for sale, sale, marketing, distributing, and/or importation of Apotex's ANDA Product immediately and imminently upon approval of the Apotex ANDA.

393. Unless enjoined by this Court, Apotex intends to, and will, actively induce infringement of the '438 patent when the Apotex ANDA is approved, and intends to, and will do so, immediately and imminently upon approval.

394. Apotex knows that Apotex's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '438 patent, and that Apotex's ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. Unless enjoined by this Court, Apotex intends to, and will, contribute to the infringement of the '438 patent immediately and imminently upon approval of the Apotex ANDA.

395. The foregoing actions by Apotex prior to the expiration of the '438 patent constitute and/or will constitute infringement, active inducement of infringement, and/or contribution to the infringement by others under 35 U.S.C. §§ 271(a), (b) and/or (c).

396. Apotex had knowledge of the '438 patent and is knowingly and willfully infringing the '438 patent.

397. Apotex acted without a reasonable basis for believing that it would not be liable for infringing the '438 patent, actively inducing infringement of the '438 patent, and/or contributing to the infringement by others of the '438 patent.

398. Unless Apotex is enjoined from infringing the '438 patent, actively inducing infringement of the '438 patent, and/or contributing to the infringement of the '438 patent, Janssen will suffer irreparable injury for which Janssen has no adequate remedy at law. Pursuant

to 35 U.S.C. § 271(e)(4)(B) and 283 and Rule 65, Fed. R. Civ. P., a preliminary and permanent injunction should be entered preventing further infringement.

399. Janssen is entitled to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court that the FDA set the effective date of approval for Apotex's ANDA No. 208453 be a date which is not earlier than the date on which the '438 patent expire or any later expiration of exclusivity to which Janssen is or becomes entitled.

400. This case is "exceptional," as that term is used in 35 U.S.C. § 285.

COUNT V: INFRINGEMENT OF THE '438 PATENT BY CITRON PHARMA

401. Janssen incorporates the preceding paragraphs as if fully set forth herein.

402. The use of Citron Pharma's ANDA Product is covered by one or more claims of the '438 patent.

403. The submission of Citron Pharma's ANDA No. 208371 with a Paragraph IV certification regarding the '438 patent for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Citron Pharma's ANDA Product before the expiration of the '438 patent constitutes infringement of one or more of the claims of the '438 patent under 35 U.S.C. § 271(e)(2).

404. The commercial manufacture, use, offer for sale, sale, marketing, distributing, and/or importation of Citron Pharma's ANDA Product before the expiration of the '438 patent would infringe one or more claims of the '438 patent under 35 U.S.C. § 271.

405. The use of Citron Pharma's ANDA Product in accordance with and as directed by Citron Pharma's proposed labeling for that product before the expiration of the '438 patent would infringe one or more claims of the '438 patent under 35 U.S.C. § 271.

406. Unless enjoined by this Court, Citron Pharma intends to, and will, engage in the manufacture, use, offer for sale, sale, marketing, distributing, and/or importation of Citron Pharma's ANDA Product immediately and imminently upon approval of the Citron Pharma ANDA.

407. Unless enjoined by this Court, Citron Pharma intends to, and will, actively induce infringement of the '438 patent when the Citron Pharma ANDA is approved, and intends to, and will, do so immediately and imminently upon approval.

408. Citron Pharma knows that Citron Pharma's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '438 patent, and that Citron Pharma's ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. Unless enjoined by this Court, Citron Pharma intends to, and will, contribute to the infringement of the '438 patent immediately and imminently upon approval of the Citron Pharma ANDA.

409. The foregoing actions by Citron Pharma prior to the expiration of the '438 patent constitute and/or will constitute infringement, active inducement of infringement, and/or contribution to the infringement by others under 35 U.S.C. §§ 271(a), (b) and/or (c).

410. Citron Pharma had knowledge of the '438 patent and is knowingly and willfully infringing the '438 patent.

411. Citron Pharma acted without a reasonable basis for believing that it would not be liable for infringing the '438 patent, actively inducing infringement of the '438 patent, and/or contributing to the infringement by others of the '438 patent.

412. Unless Citron Pharma is enjoined from infringing the '438 patent, actively inducing infringement of the '438 patent, and/or contributing to the infringement of the '438

patent, Janssen will suffer irreparable injury for which Janssen has no an adequate remedy at law. Pursuant to 35 U.S.C. § 271(e)(4)(B) and 283 and Rule 65, Fed. R. Civ. P., a preliminary and permanent injunction should be entered preventing further infringement.

413. Janssen is entitled to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court that the FDA set the effective date of approval for Citron Pharma's ANDA No. 208371 to be a date which is not earlier than the date on which the '438 patent expires or any later expiration of exclusivity to which Janssen is or becomes entitled.

414. This case is "exceptional," as that term is used in 35 U.S.C. § 285.

COUNT VI: INFRINGEMENT OF THE '438 PATENT BY DRL

415. Janssen incorporates the preceding paragraphs as if fully set forth herein.

416. The use of DRL's ANDA Product is covered by one or more claims of the '438 patent.

417. The submission of DRL's ANDA No. 208416 with a Paragraph IV certification regarding the '438 patent for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of DRL's ANDA Product before the expiration of the '438 patent constitutes infringement of one or more of the claims of the '438 patent under 35 U.S.C. § 271(e)(2).

418. The commercial manufacture, use, offer for sale, sale, marketing, distributing, and/or importation of DRL's ANDA Product before the expiration of the '438 patent would infringe one or more claims of the '438 patent under 35 U.S.C. § 271.

419. The use of DRL's ANDA Product in accordance with and as directed by DRL's proposed labeling for that product before the expiration of the '438 patent would infringe one or more claims of the '438 patent under 35 U.S.C. § 271.

420. Unless enjoined by this Court, DRL intends to, and will, engage in the manufacture, use, offer for sale, sale, marketing, distributing, and/or importation of DRL's ANDA Product immediately and imminently upon approval of the DRL ANDA.

421. Unless enjoined by this Court, DRL intends to, and will, actively induce infringement of the '438 patent when the DRL ANDA is approved, and intends to, and will, do so immediately and imminently upon approval.

422. DRL knows that DRL's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '438 patent, and that DRL's ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. Unless enjoined by this Court, DRL intends to, and will, contribute to the infringement of the '438 patent immediately and imminently upon approval of the DRL ANDA.

423. The foregoing actions by DRL prior to the expiration of the '438 patent constitute and/or will constitute infringement, active inducement of infringement, and/or contribution to the infringement by others under 35 U.S.C. §§ 271(a), (b) and/or (c).

424. DRL had knowledge of the '438 patent and is knowingly and willfully infringing the '438 patent.

425. DRL acted without a reasonable basis for believing that it would not be liable for infringing the '438 patent, actively inducing infringement of the '438 patent, and/or contributing to the infringement by others of the '438 patent.

426. Unless DRL is enjoined from infringing the '438 patent, actively inducing infringement of the '438 patent, and/or contributing to the infringement of the '438 patent, Janssen will suffer irreparable injury for which Janssen has no adequate remedy at law. Pursuant

to 35 U.S.C. § 271(e)(4)(B) and 283 and Rule 65, Fed. R. Civ. P., a preliminary and permanent injunction should be entered preventing further infringement.

427. Janssen is entitled to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court that the FDA set the effective date of approval for DRL's ANDA No. 208416 to be a date which is not earlier than the date on which the '438 patent expires or any later expiration of exclusivity to which Janssen is or becomes entitled.

428. This case is "exceptional," as that term is used in 35 U.S.C. § 285.

COUNT VII: INFRINGEMENT OF THE '438 PATENT BY MYLAN

429. Janssen incorporates the preceding paragraphs as if fully set forth herein.

430. The use of Mylan's ANDA Product is covered by one or more claims of the '438 patent.

431. The submission of Mylan's ANDA No. 208446 with a Paragraph IV certification regarding the '438 patent for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Mylan's ANDA Product before the expiration of the '438 patent constitutes infringement of one or more of the claims of the '438 patent under 35 U.S.C. § 271(e)(2).

432. The commercial manufacture, use, offer for sale, sale, marketing, distributing, and/or importation of Mylan's ANDA Product before the expiration of the '438 patent would infringe one or more claims of the '438 patent under 35 U.S.C. § 271.

433. The use of Mylan's ANDA Product in accordance with and as directed by Mylan's proposed labeling for that product before the expiration of the '438 patent would infringe one or more claims of the '438 patent under 35 U.S.C. § 271.

434. Unless enjoined by this Court, Mylan intends to, and will, engage in the manufacture, use, offer for sale, sale, marketing, distributing, and/or importation of Mylan's ANDA Product immediately and imminently upon approval of the Mylan ANDA.

435. Unless enjoined by this Court, Mylan intends to, and will, actively induce infringement of the '438 patent when the Mylan ANDA is approved, and intends to, and will, do so immediately and imminently upon approval.

436. Mylan knows that Mylan's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '438 patent, and that Mylan's ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. Unless enjoined by this Court, Mylan intends to, and will, contribute to the infringement of the '438 patent immediately and imminently upon approval of the Mylan ANDA.

437. The foregoing actions by Mylan prior to the expiration of the '438 patent constitute and/or will constitute infringement, active inducement of infringement, and/or contribution to the infringement by others under 35 U.S.C. §§ 271(a), (b) and/or (c).

438. Mylan had knowledge of the '438 patent and is knowingly and willfully infringing the '438 patent.

439. Mylan acted without a reasonable basis for believing that it would not be liable for infringing the '438 patent, actively inducing infringement of the '438 patent, and/or contributing to the infringement by others of the '438 patent.

440. Unless Mylan is enjoined from infringing the '438 patent, actively inducing infringement of the '438 patent, and/or contributing to the infringement of the '438 patent, Janssen will suffer irreparable injury for which Janssen has no adequate remedy at law. Pursuant

to 35 U.S.C. § 271(e)(4)(B) and 283 and Rule 65, Fed. R. Civ. P., a preliminary and permanent injunction should be entered preventing further infringement.

441. Janssen is entitled to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court that the FDA set the effective date of approval for Mylan's ANDA No. 208446 to be a date which is not earlier than the date on which the '438 patent expires or any later expiration of exclusivity to which Janssen is or becomes entitled.

442. This case is "exceptional," as that term is used in 35 U.S.C. § 285.

COUNT VIII: INFRINGEMENT OF THE '438 PATENT BY PAR

443. Janssen incorporates the preceding paragraphs as if fully set forth herein.

444. The use of Par's ANDA Product is covered by one or more claims of the '438 patent.

445. The submission of Par's ANDA No. 208168 with a Paragraph IV certification regarding the '438 patent for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Par's ANDA Product before the expiration of the '438 patent constitutes infringement of one or more of the claims of the '438 patent under 35 U.S.C. § 271(e)(2).

446. The commercial manufacture, use, offer for sale, sale, marketing, distributing, and/or importation of Par's ANDA Product before the expiration of the '438 patent would infringe one or more claims of the '438 patent under 35 U.S.C. § 271.

447. The use of Par's ANDA Product in accordance with and as directed by Par's proposed labeling for that product before the expiration of the '438 patent would infringe one or more claims of the '438 patent under 35 U.S.C. § 271.

448. Unless enjoined by this Court, Par intends to, and will, engage in the manufacture, use, offer for sale, sale, marketing, distributing, and/or importation of Par's ANDA Product immediately and imminently upon approval of the Par ANDA.

449. Unless enjoined by this Court, Par intends to, and will, actively induce infringement of the '438 patent when the Par ANDA is approved, and intends to, and will do so, immediately and imminently upon approval.

450. Par knows that Par's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '438 patent, and that Par's ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. Unless enjoined by this Court, Par intends to, and will, contribute to the infringement of the '438 patent immediately and imminently upon approval of the Par ANDA.

451. The foregoing actions by Par prior to the expiration of the '438 patent constitute and/or will constitute infringement, active inducement of infringement, and/or contribution to the infringement by others under 35 U.S.C. §§ 271(a), (b) and/or (c).

452. Par had knowledge of the '438 patent and is knowingly and willfully infringing the '438 patent.

453. Par acted without a reasonable basis for believing that it would not be liable for infringing the '438 patent, actively inducing infringement of the '438 patent, and/or contributing to the infringement by others of the '438 patent.

454. Unless Par is enjoined from infringing the '438 patent, actively inducing infringement of the '438 patent, and/or contributing to the infringement of the '438 patent, Janssen will suffer irreparable injury for which Janssen has no adequate remedy at law. Pursuant

to 35 U.S.C. § 271(e)(4)(B) and 283 and Rule 65, Fed. R. Civ. P., a preliminary and permanent injunction should be entered preventing further infringement.

455. Janssen is entitled to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court that the FDA set the effective date of approval for Par's ANDA No. 208168 to be a date which is not earlier than the date on which the '438 patent expires or any later expiration of exclusivity to which Janssen is or becomes entitled.

456. This case is "exceptional," as that term is used in 35 U.S.C. § 285.

COUNT IX: INFRINGEMENT OF THE '438 PATENT BY SUN

457. Janssen incorporates the preceding paragraphs as if fully set forth herein.

458. The use of Sun's ANDA Product is covered by one or more claims of the '438 patent.

459. The submission of Sun's ANDA No. 208440 with a Paragraph IV certification regarding the '438 patent for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Sun's ANDA Product before the expiration of the '438 patent constitutes infringement of one or more of the claims of the '438 patent under 35 U.S.C. § 271(e)(2).

460. The commercial manufacture, use, offer for sale, sale, marketing, distributing, and/or importation of Sun's ANDA Product before the expiration of the '438 patent would infringe one or more claims of the '438 patent under 35 U.S.C. § 271.

461. The use of Sun's ANDA Product in accordance with and as directed by Sun's proposed labeling for that product before the expiration of the '438 patent would infringe one or more claims of the '438 patent under 35 U.S.C. § 271.

462. Unless enjoined by this Court, Sun intends to, and will, engage in the manufacture, use, offer for sale, sale, marketing, distributing, and/or importation of Sun's ANDA Product immediately and imminently upon approval of the Sun ANDA.

463. Unless enjoined by this Court, Sun intends to, and will, actively induce infringement of the '438 patent when the Sun ANDA is approved, and intends to, and will, do so immediately and imminently upon approval.

464. Sun knows that Sun's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '438 patent, and that Sun's ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. Unless enjoined by this Court, Sun intends to, and will, contribute to the infringement of the '438 patent immediately and imminently upon approval of the Sun ANDA.

465. The foregoing actions by Sun prior to the expiration of the '438 patent constitute and/or will constitute infringement, active inducement of infringement, and/or contribution to the infringement by others under 35 U.S.C. §§ 271(a), (b) and/or (c).

466. Sun had knowledge of the '438 patent and is knowingly and willfully infringing the '438 patent.

467. Sun acted without a reasonable basis for believing that it would not be liable for infringing the '438 patent, actively inducing infringement of the '438 patent, and/or contributing to the infringement by others of the '438 patent.

468. Unless Sun is enjoined from infringing the '438 patent, actively inducing infringement of the '438 patent, and/or contributing to the infringement of the '438 patent, Janssen will suffer irreparable injury for which Janssen has no adequate remedy at law. Pursuant

to 35 U.S.C. § 271(e)(4)(B) and 283 and Rule 65, Fed. R. Civ. P., a preliminary and permanent injunction should be entered preventing further infringement.

469. Janssen is entitled to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court that the FDA set the effective date of approval for Sun's ANDA No. 208440 to be a date which is not earlier than the date on which the '438 patent expires or any later expiration of exclusivity to which Janssen is or becomes entitled.

470. This case is "exceptional," as that term is used in 35 U.S.C. § 285.

COUNT X: INFRINGEMENT OF THE '438 PATENT BY TEVA

471. Janssen incorporates the preceding paragraphs as if fully set forth herein.

472. The use of Teva's ANDA Product is covered by one or more claims of the '438 patent.

473. The submission of Teva's ANDA No. 208432 with a Paragraph IV certification regarding the '438 patent for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Teva's ANDA Product before the expiration of the '438 patent constitutes infringement of one or more of the claims of the '438 patent under 35 U.S.C. § 271(e)(2).

474. The commercial manufacture, use, offer for sale, sale, marketing, distributing, and/or importation of Teva's ANDA Product before the expiration of the '438 patent would infringe one or more claims of the '438 patent under 35 U.S.C. § 271.

475. The use of Teva's ANDA Product in accordance with and as directed by Teva's proposed labeling for that product before the expiration of the '438 patent would infringe one or more claims of the '438 patent under 35 U.S.C. § 271.

476. Unless enjoined by this Court, Teva intends to, and will, engage in the manufacture, use, offer for sale, sale, marketing, distributing, and/or importation of Teva's ANDA Product immediately and imminently upon approval of the Teva ANDA.

477. Unless enjoined by this Court, Teva intends to, and will, actively induce infringement of the '438 patent when the Teva ANDA is approved, and intends to, and will, do so immediately and imminently upon approval.

478. Teva knows that Teva's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '438 patent, and that Teva's ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. Unless enjoined by this Court, Teva intends to, and will, contribute to the infringement of the '438 patent immediately and imminently upon approval of the Teva ANDA.

479. The foregoing actions by Teva prior to the expiration of the '438 patent constitute and/or will constitute infringement, active inducement of infringement, and/or contribution to the infringement by others under 35 U.S.C. §§ 271(a), (b) and/or (c).

480. Teva had knowledge of the '438 patent and is knowingly and willfully infringing the '438 patent.

481. Teva acted without a reasonable basis for believing that it would not be liable for infringing the '438 patent, actively inducing infringement of the '438 patent, and/or contributing to the infringement by others of the '438 patent.

482. Unless Teva is enjoined from infringing the '438 patent, actively inducing infringement of the '438 patent, and/or contributing to the infringement of the '438 patent, Janssen will suffer irreparable injury for which Janssen has no adequate remedy at law. Pursuant

to 35 U.S.C. § 271(e)(4)(B) and 283 and Rule 65, Fed. R. Civ. P., a preliminary and permanent injunction should be entered preventing further infringement.

483. Janssen is entitled to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court that the FDA set the effective date of approval for Teva's ANDA No. 208432 to be a date which is not earlier than the date on which the '438 patent expires or any later expiration of exclusivity to which Janssen is or becomes entitled.

484. This case is "exceptional," as that term is used in 35 U.S.C. § 285.

COUNT XI: INFRINGEMENT OF THE '438 PATENT BY HIKMA/WEST-WARD

485. Janssen incorporates the preceding paragraphs as if fully set forth herein.

486. The use of Hikma/West-Ward's ANDA Product is covered by one or more claims of the '438 patent.

487. The submission of Hikma/West-Ward's ANDA No. 208339 with a Paragraph IV certification regarding the '438 patent for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Hikma/West-Ward's ANDA Product before the expiration of the '438 patent constitutes infringement of one or more of the claims of the '438 patent under 35 U.S.C. § 271(e)(2).

488. The commercial manufacture, use, offer for sale, sale, marketing, distributing, and/or importation of Hikma/West-Ward's ANDA Product before the expiration of the '438 patent would infringe one or more claims of the '438 patent under 35 U.S.C. § 271.

489. The use of Hikma/West-Ward's ANDA Product in accordance with and as directed by Hikma/West-Ward's proposed labeling for that product before the expiration of the '438 patent would infringe one or more claims of the '438 patent under 35 U.S.C. § 271.

490. Unless enjoined by this Court, Hikma/West-Ward intends to, and will, engage in the manufacture, use, offer for sale, sale, marketing, distributing, and/or importation of Hikma/West-Ward's ANDA Product immediately and imminently upon approval of the Hikma/West-Ward ANDA.

491. Unless enjoined by this Court, Hikma/West-Ward intends to, and will, actively induce infringement of the '438 patent when the Hikma/West-Ward ANDA is approved, and intends to, and will, do so immediately and imminently upon approval.

492. Hikma/West-Ward knows that Hikma/West-Ward's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '438 patent, and that Hikma/West-Ward's ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. Unless enjoined by this Court, Hikma/West-Ward intends to, and will, contribute to the infringement of the '438 patent immediately and imminently upon approval of the Hikma/West-Ward ANDA.

493. The foregoing actions by Hikma/West-Ward prior to the expiration of the '438 patent constitute and/or will constitute infringement, active inducement of infringement, and/or contribution to the infringement by others under 35 U.S.C. §§ 271(a), (b) and/or (c).

494. Hikma/West-Ward had knowledge of the '438 patent and is knowingly and willfully infringing the '438 patent.

495. Hikma/West-Ward acted without a reasonable basis for believing that it would not be liable for infringing the '438 patent, actively inducing infringement of the '438 patent, and/or contributing to the infringement by others of the '438 patent.

496. Unless Hikma/West-Ward is enjoined from infringing the '438 patent, actively inducing infringement of the '438 patent, and/or contributing to the infringement of the '438

patent, Janssen will suffer irreparable injury for which Janssen has no adequate remedy at law. Pursuant to 35 U.S.C. § 271(e)(4)(B) and 283 and Rule 65, Fed. R. Civ. P., a preliminary and permanent injunction should be entered preventing further infringement.

497. Janssen is entitled to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court that the FDA set the effective date of approval for Hikma/West-Ward's ANDA No. 208339 to be a date which is not earlier than the date on which the '438 patent expires or any later expiration of exclusivity to which Janssen is or becomes entitled.

498. This case is "exceptional," as that term is used in 35 U.S.C. § 285.

COUNT XII: INFRINGEMENT OF THE '438 PATENT BY WOCKHARDT

499. Janssen incorporates the preceding paragraphs as if fully set forth herein.

500. The use of Wockhardt's ANDA Product is covered by one or more claims of the '438 patent.

501. The submission of Wockhardt's ANDA No. 208380 with a Paragraph IV certification regarding the '438 patent for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Wockhardt's ANDA Product before the expiration of the '438 patent constitutes infringement of one or more of the claims of the '438 patent under 35 U.S.C. § 271(e)(2).

502. The commercial manufacture, use, offer for sale, sale, marketing, distributing, and/or importation of Wockhardt's ANDA Product before the expiration of the '438 patent would infringe one or more claims of the '438 patent under 35 U.S.C. § 271.

503. The use of Wockhardt's ANDA Product in accordance with and as directed by Wockhardt's proposed labeling for that product before the expiration of the '438 patent would infringe one or more claims of the '438 patent under 35 U.S.C. § 271.

504. Unless enjoined by this Court, Wockhardt intends to, and will, engage in the manufacture, use, offer for sale, sale, marketing, distributing, and/or importation of Wockhardt's ANDA Product immediately and imminently upon approval of the Wockhardt ANDA.

505. Unless enjoined by this Court, Wockhardt intends to, and will, actively induce infringement of the '438 patent when the Wockhardt ANDA is approved, and intends to, and will, do so immediately and imminently upon approval.

506. Wockhardt knows that Wockhardt's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '438 patent, and that Wockhardt's ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. Unless enjoined by this Court, Wockhardt intends to, and will, contribute to the infringement of the '438 patent immediately and imminently upon approval of the Wockhardt ANDA.

507. The foregoing actions by Wockhardt prior to the expiration of the '438 patent constitute and/or will constitute infringement, active inducement of infringement, and/or contribution to the infringement by others under 35 U.S.C. §§ 271(a), (b) and/or (c).

508. Wockhardt had knowledge of the '438 patent and is knowingly and willfully infringing the '438 patent.

509. Wockhardt acted without a reasonable basis for believing that it would not be liable for infringing the '438 patent, actively inducing infringement of the '438 patent, and/or contributing to the infringement by others of the '438 patent.

510. Unless Wockhardt is enjoined from infringing the '438 patent, actively inducing infringement of the '438 patent, and/or contributing to the infringement of the '438 patent, Janssen will suffer irreparable injury for which Janssen has no adequate remedy at law. Pursuant

to 35 U.S.C. § 271(e)(4)(B) and 283 and Rule 65, Fed. R. Civ. P., a preliminary and permanent injunction should be entered preventing further infringement.

511. Janssen is entitled to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court that the FDA set the effective date of approval for Wockhardt's ANDA No. 208380 to be a date which is not earlier than the date on which the '438 patent expire or any later expiration of exclusivity to which Janssen is or becomes entitled.

512. This case is "exceptional," as that term is used in 35 U.S.C. § 285.

COUNT XIII: INFRINGEMENT OF THE '438 PATENT BY HETERO

513. Janssen incorporates the preceding paragraphs as if fully set forth herein.

514. The use of Hetero's ANDA Product is covered by one or more claims of the '438 patent.

515. The submission of Hetero's ANDA No. 208349 with a Paragraph IV certification regarding the '438 patent for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Hetero's ANDA Product before the expiration of the '438 patent constitutes infringement of one or more of the claims of the '438 patent under 35 U.S.C. § 271(e)(2).

516. The commercial manufacture, use, offer for sale, sale, marketing, distributing, and/or importation of Hetero's ANDA Product before the expiration of the '438 patent would infringe one or more claims of the '438 patent under 35 U.S.C. § 271.

517. The use of Hetero's ANDA Product in accordance with and as directed by Hetero's proposed labeling for that product before the expiration of the '438 patent would infringe one or more claims of the '438 patent under 35 U.S.C. § 271.

518. Unless enjoined by this Court, Hetero intends to, and will, engage in the manufacture, use, offer for sale, sale, marketing, distributing, and/or importation of Hetero's ANDA Product immediately and imminently upon approval of the Hetero ANDA.

519. Unless enjoined by this Court, Hetero intends to, and will, actively induce infringement of the '438 patent when the Hetero ANDA is approved, and intends to, and will, do so immediately and imminently upon approval.

520. Hetero knows that Hetero's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '438 patent, and that Hetero's ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. Unless enjoined by this Court, Hetero intends to, and will, contribute to the infringement of the '438 patent immediately and imminently upon approval of the Hetero ANDA.

521. The foregoing actions by Hetero prior to the expiration of the '438 patent constitute and/or will constitute infringement, active inducement of infringement, and/or contribution to the infringement by others under 35 U.S.C. §§ 271(a), (b) and/or (c).

522. Hetero had knowledge of the '438 patent and is knowingly and willfully infringing the '438 patent.

523. Hetero acted without a reasonable basis for believing that it would not be liable for infringing the '438 patent, actively inducing infringement of the '438 patent, and/or contributing to the infringement by others of the '438 patent.

524. Unless Hetero is enjoined from infringing the '438 patent, actively inducing infringement of the '438 patent, and/or contributing to the infringement of the '438 patent, Janssen will suffer irreparable injury for which Janssen has no adequate remedy at law. Pursuant to 35 U.S.C. §§ 271(e)(4)(B) and 283, as well as Rule 65 of the Federal Rules of Civil

Procedure, a preliminary and permanent injunction should be entered preventing further infringement.

525. Janssen is entitled to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court that the FDA set the effective date of approval for Hetero's ANDA No. 208349 to be a date which is not earlier than the date on which the '438 patent expires or any later expiration of exclusivity to which Janssen is or becomes entitled.

526. This case is "exceptional," as that term is used in 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs request the following relief:

A. Judgment in favor of Plaintiffs and against Defendants.

B. Judgment that the '213 patent is valid and enforceable;

C. Judgment that the '438 patent is valid and enforceable;

D. **As Against Actavis:**

(1) Judgment that Actavis has infringed, literally or by the doctrine of equivalents, the '213 patent by the submission of ANDA No. 208274, and that the commercial manufacture, use, sale, offer for sale, marketing, distribution, or importation of Actavis's ANDA Product, in the United States, will constitute infringement, contributory infringement, and actively inducing infringement of the '213 patent;

(2) Judgment that Actavis has infringed, literally or by the doctrine of equivalents, the '438 patent by the submission of ANDA No. 208274, and that the commercial manufacture, use, sale, offer for sale, marketing, distribution, or importation of Actavis's ANDA Product, in the United States, will constitute infringement, contributory infringement, and actively inducing infringement of the '438 patent;

(3) Judgment, pursuant to 35 U.S.C. §271(e)(4)(A), that the effective date of any FDA approval of Actavis's ANDA No. 208274 shall be no earlier than the date of expiration of the last expiring '213 and '438 patents and any additional periods of exclusivity to which Plaintiffs are or become entitled;

(4) A preliminary and permanent injunction, pursuant to 35 U.S.C. § 271(e)(4)(B) and 283 and Rule 65, Fed. R. Civ. P., enjoining Actavis, its officers, partners, agents, servants, employees, parents, subsidiaries, divisions, affiliate corporations, other related business entities and all other persons acting in concert, participation, or privity with it, and their successors and assigns, from making, using, selling, offering to sell, marketing, distributing, or importing into the United States Actavis's ANDA Product and the active ingredient described in Actavis's ANDA No. 208274, and any product that is similar to or only colorably different from those products, and from infringing, contributorily infringing, or inducing others to infringe the '213 patent, before the expiration of the '213 patent and any additional periods of exclusivity;

(5) A preliminary and permanent injunction, pursuant to 35 U.S.C. §271(e)(4)(B) and 283 and Rule 65, Fed. R. Civ. P., enjoining Actavis, its officers, partners, agents, servants, employees, parents, subsidiaries, affiliate corporations, other business entities and all other persons acting in concert, participation or privity with it, their successors and assigns, from making, using, selling, offering to sell, marketing, distributing, or importing into the United States Actavis's ANDA Product and any product that is similar to or only colorably different from those products, and from infringing, contributorily infringing, or inducing others to infringe the '438 patent, before the expiration of the '438 patent and any additional periods of exclusivity;

(6) Damages or other monetary relief, including prejudgment and post-judgment interest, if Actavis engages in the commercial manufacture, use, sale, offer to sell, marketing, distribution, or importation of Actavis's ANDA Product, or any product or compound that infringes the '213 and '438 patents, or in inducement or contribution of the '213 and '438 patents, before the expiration of the '213 and '438 patents and any additional periods of exclusivity;

(7) A declaration that this is an exceptional case and an award of reasonable attorneys' fees and expenses to Plaintiffs pursuant to 35 U.S.C. §§ 271(e)(4) and 285;

(8) Plaintiffs' reasonable costs of suit incurred in bringing and prosecuting this action; and

(9) Such further and other relief as this Court may deem just and proper.

E. **As Against Amneal:**

(1) Judgment that Amneal has infringed, literally or by the doctrine of equivalents, the '438 patent by the submission of ANDA No. 208327, and that the commercial manufacture, use, sale, offer for sale, marketing, distribution, or importation of Amneal's ANDA Product, in the United States, will constitute infringement, contributory infringement, and actively inducing infringement of the '438 patent;

(2) Judgment, pursuant to 35 U.S.C. §271(e)(4)(A), that the effective date of any FDA approval of Amneal's ANDA No. 208327 shall be no earlier than the date of expiration of the '438 patent and any additional periods of exclusivity to which Plaintiffs are or become entitled;

(3) A preliminary and permanent injunction, pursuant to 35 U.S.C. §271(e)(4)(B) and 283 and Rule 65, Fed. R. Civ. P., enjoining Amneal, its officers, partners,

agents, servants, employees, parents, subsidiaries, divisions, affiliate corporations, other related business entities and all other persons acting in concert, participation, or privity with it, and their successors and assigns, from making, using, selling, offering to sell, marketing, distributing, or importing into the United States Amneal's ANDA Product and the active ingredient described in Amneal's ANDA No. 208327, and any product that is similar to or only colorably different from those products, and from infringing, contributorily infringing, or inducing others to infringe the '438 patent, before the expiration of the '438 patent and any additional periods of exclusivity;

(4) Damages or other monetary relief, including prejudgment and post-judgment interest, if Amneal engages in the commercial manufacture, use, sale, offer to sell, marketing, distribution, or importation of Amneal's ANDA Product, or any product or compound that infringes the '438 patent, or in inducement or contribution of the '438 patent, before the expiration of the '438 patent and any additional periods of exclusivity;

(5) A declaration that this is an exceptional case and an award of reasonable attorneys' fees and expenses to Plaintiffs pursuant to 35 U.S.C. §§ 271(e)(4) and 285;

(6) Plaintiffs' reasonable costs of suit incurred in bringing and prosecuting this action; and

(7) Such further and other relief as this Court may deem just and proper.

F. **As Against Apotex:**

(1) Judgment that Apotex has infringed, literally or by the doctrine of equivalents, the '438 patent by the submission of ANDA No. 208453, and that the commercial manufacture, use, sale, offer for sale, marketing, distribution, or importation of Apotex's ANDA Product, in the United States, will constitute infringement, contributory infringement, and actively inducing infringement of the '438 patent;

(2) Judgment, pursuant to 35 U.S.C. §271(e)(4)(A), that the effective date of any FDA approval of Apotex's ANDA No. 208453 shall be no earlier than the date of expiration of the '438 patent and any additional periods of exclusivity to which Plaintiffs are or become entitled;

(3) A preliminary and permanent injunction, pursuant to 35 U.S.C. §271(e)(4)(B) and 283 and Rule 65, Fed. R. Civ. P., enjoining Apotex, its officers, partners, agents, servants, employees, parents, subsidiaries, divisions, affiliate corporations, other related business entities and all other persons acting in concert, participation, or privity with it, and their successors and assigns, from making, using, selling, offering to sell, marketing, distributing, or importing into the United States Apotex's ANDA Product and the active ingredient described in Apotex's ANDA No. 208453, and any product that is similar to or only colorably different from those products, and from infringing, contributorily infringing, or inducing others to infringe the '438 patent, before the expiration of the '438 patent and any additional periods of exclusivity;

(4) Damages or other monetary relief, including prejudgment and post-judgment interest, if Apotex engages in the commercial manufacture, use, sale, offer to sell, marketing, distribution, or importation of Apotex's ANDA Product, or any product or compound that infringes the '438 patent, or in inducement or contribution of the '438 patent, before the expiration of the '438 patent and any additional periods of exclusivity;

(5) A declaration that this is an exceptional case and an award of reasonable attorneys' fees and expenses to Plaintiffs pursuant to 35 U.S.C. §§ 271(e)(4) and 285;

(6) Plaintiffs' reasonable costs of suit incurred in bringing and prosecuting this action; and

(7) Such further and other relief as this Court may deem just and proper.

G. **As Against Citron Pharma:**

(1) Judgment that Citron Pharma has infringed, literally or by the doctrine of equivalents, the ’438 patent by the submission of ANDA No. 208371, and that the commercial manufacture, use, sale, offer for sale, marketing, distribution, or importation of Citron Pharma’s ANDA Product, in the United States, will constitute infringement, contributory infringement, and actively inducing infringement of the ’438 patent;

(2) Judgment, pursuant to 35 U.S.C. §271(e)(4)(A), that the effective date of any FDA approval of Citron Pharma’s ANDA No. 208371 shall be no earlier than the date of expiration of the ’438 patent and any additional periods of exclusivity to which Plaintiffs are or become entitled;

(3) A preliminary and permanent injunction, pursuant to 35 U.S.C. §271(e)(4)(B) and 283 and Rule 65, Fed. R. Civ. P., enjoining Citron Pharma, its officers, partners, agents, servants, employees, parents, subsidiaries, divisions, affiliate corporations, other related business entities and all other persons acting in concert, participation, or privity with it, and their successors and assigns, from making, using, selling, offering to sell, marketing, distributing, or importing into the United States Citron Pharma’s ANDA Product and the active ingredient described in Citron Pharma’s ANDA No. 208371, and any product that is similar to or only colorably different from those products, and from infringing, contributorily infringing, or inducing others to infringe the ’438 patent, before the expiration of the ’438 patent and any additional periods of exclusivity;

(4) Damages or other monetary relief, including prejudgment and post-judgment interest, if Citron Pharma engages in the commercial manufacture, use, sale, offer to sell, marketing, distribution, or importation of Citron Pharma’s ANDA Product, or any product

or compound that infringes the ’438 patent, or in inducement or contribution of the ’438 patent, before the expiration of the ’438 patent and any additional periods of exclusivity;

(5) A declaration that this is an exceptional case and an award of reasonable attorneys’ fees and expenses to Plaintiffs pursuant to 35 U.S.C. §§ 271(e)(4) and 285;

(6) Plaintiffs’ reasonable costs of suit incurred in bringing and prosecuting this action; and

(7) Such further and other relief as this Court may deem just and proper.

H. **As Against DRL:**

(1) Judgment that DRL has infringed, literally or by the doctrine of equivalents, the ’438 patent by the submission of ANDA No. 208416, and that the commercial manufacture, use, sale, offer for sale, marketing, distribution, or importation of DRL’s ANDA Product, in the United States, will constitute infringement, contributory infringement, and actively inducing infringement of the ’438 patent;

(2) Judgment, pursuant to 35 U.S.C. §271(e)(4)(A), that the effective date of any FDA approval of DRL’s ANDA No. 208416 shall be no earlier than the date of expiration of the ’438 patent and any additional periods of exclusivity to which Plaintiffs are or become entitled;

(3) A preliminary and permanent injunction, pursuant to 35 U.S.C. §271(e)(4)(B) and 283 and Rule 65, Fed. R. Civ. P., enjoining DRL, its officers, partners, agents, servants, employees, parents, subsidiaries, divisions, affiliate corporations, other related business entities and all other persons acting in concert, participation, or privity with it, and their successors and assigns, from making, using, selling, offering to sell, marketing, distributing, or importing into the United States DRL’s ANDA Product and the active ingredient described in

DRL's ANDA No. 208416, and any product that is similar to or only colorably different from those products, and from infringing, contributorily infringing, or inducing others to infringe the '438 patent, before the expiration of the '438 patent and any additional periods of exclusivity;

(4) Damages or other monetary relief, including prejudgment and post-judgment interest, if DRL engages in the commercial manufacture, use, sale, offer to sell, marketing, distribution, or importation of DRL's ANDA Product, or any product or compound that infringes the '438 patent, or in inducement or contribution of the '438 patent, before the expiration of the '438 patent and any additional periods of exclusivity;

(5) A declaration that this is an exceptional case and an award of reasonable attorneys' fees and expenses to Plaintiffs pursuant to 35 U.S.C. §§ 271(e)(4) and 285;

(6) Plaintiffs' reasonable costs of suit incurred in bringing and prosecuting this action; and

(7) Such further and other relief as this Court may deem just and proper.

I. **As Against Mylan:**

(1) Judgment that Mylan has infringed, literally or by the doctrine of equivalents, the '438 patent by the submission of ANDA No. 208446, and that the commercial manufacture, use, sale, offer for sale, marketing, distribution, or importation of Mylan's ANDA Product, in the United States, will constitute infringement, contributory infringement, and actively inducing infringement of the '438 patent;

(2) Judgment, pursuant to 35 U.S.C. §271(e)(4)(A), that the effective date of any FDA approval of Mylan's ANDA No. 208446 shall be no earlier than the date of expiration of the '438 patent and any additional periods of exclusivity to which Plaintiffs are or become entitled;

(3) A preliminary and permanent injunction, pursuant to 35 U.S.C. §271(e)(4)(B) and 283 and Rule 65, Fed. R. Civ. P., enjoining Mylan, its officers, partners, agents, servants, employees, parents, subsidiaries, divisions, affiliate corporations, other related business entities and all other persons acting in concert, participation, or privity with it, and their successors and assigns, from making, using, selling, offering to sell, marketing, distributing, or importing into the United States Mylan's ANDA Product and the active ingredient described in Mylan's ANDA No. 208446, and any product that is similar to or only colorably different from those products, and from infringing, contributorily infringing, or inducing others to infringe the '438 patent, before the expiration of the '438 patent and any additional periods of exclusivity;

(4) Damages or other monetary relief, including prejudgment and post-judgment interest, if Mylan engages in the commercial manufacture, use, sale, offer to sell, marketing, distribution, or importation of Mylan's ANDA Product, or any product or compound that infringes the '438 patent, or in inducement or contribution of the '438 patent, before the expiration of the '438 patent and any additional periods of exclusivity;

(5) A declaration that this is an exceptional case and an award of reasonable attorneys' fees and expenses to Plaintiffs pursuant to 35 U.S.C. §§ 271(e)(4) and 285;

(6) Plaintiffs' reasonable costs of suit incurred in bringing and prosecuting this action; and

(7) Such further and other relief as this Court may deem just and proper.

J. **As Against Par:**

(1) Judgment that Par has infringed, literally or by the doctrine of equivalents, the '438 patent by the submission of ANDA No. 208168, and that the commercial manufacture, use, sale, offer for sale, marketing, distribution, or importation of Par's ANDA Product, in the

United States, will constitute infringement, contributory infringement, and actively inducing infringement of the ’438 patent;

(2) Judgment, pursuant to 35 U.S.C. §271(e)(4)(A), that the effective date of any FDA approval of Par’s ANDA No. 208168 shall be no earlier than the date of expiration of the ’438 patent and any additional periods of exclusivity to which Plaintiffs are or become entitled;

(3) A preliminary and permanent injunction, pursuant to 35 U.S.C. §271(e)(4)(B) and 283 and Rule 65, Fed. R. Civ. P., enjoining Par, its officers, partners, agents, servants, employees, parents, subsidiaries, divisions, affiliate corporations, other related business entities and all other persons acting in concert, participation, or privity with it, and their successors and assigns, from making, using, selling, offering to sell, marketing, distributing, or importing into the United States Par’s ANDA Product and the active ingredient described in Par’s ANDA No. 208168, and any product that is similar to or only colorably different from those products, and from infringing, contributorily infringing, or inducing others to infringe the ’438 patent, before the expiration of the ’438 patent and any additional periods of exclusivity;

(4) Damages or other monetary relief, including prejudgment and post-judgment interest, if Par engages in the commercial manufacture, use, sale, offer to sell, marketing, distribution, or importation of Par’s ANDA Product, or any product or compound that infringes the ’438 patent, or in inducement or contribution of the ’438 patent, before the expiration of the ’438 patent and any additional periods of exclusivity;

(5) A declaration that this is an exceptional case and an award of reasonable attorneys’ fees and expenses to Plaintiffs pursuant to 35 U.S.C. §§ 271(e)(4) and 285;

(6) Plaintiffs' reasonable costs of suit incurred in bringing and prosecuting this action; and

(7) Such further and other relief as this Court may deem just and proper.

K. **As Against Sun:**

(1) Judgment that Sun has infringed, literally or by the doctrine of equivalents, the '438 patent by the submission of ANDA No. 208440, and that the commercial manufacture, use, sale, offer for sale, marketing, distribution, or importation of Sun's ANDA Product, in the United States, will constitute infringement, contributory infringement, and actively inducing infringement of the '438 patent;

(2) Judgment, pursuant to 35 U.S.C. §271(e)(4)(A), that the effective date of any FDA approval of Sun's ANDA No. 208440 shall be no earlier than the date of expiration of the '438 patent and any additional periods of exclusivity to which Plaintiffs are or become entitled;

(3) A preliminary and permanent injunction, pursuant to 35 U.S.C. §271(e)(4)(B) and 283 and Rule 65, Fed. R. Civ. P., enjoining Sun, its officers, partners, agents, servants, employees, parents, subsidiaries, divisions, affiliate corporations, other related business entities and all other persons acting in concert, participation, or privity with it, and their successors and assigns, from making, using, selling, offering to sell, marketing, distributing, or importing into the United States Sun's ANDA Product and the active ingredient described in Sun's ANDA No. 208440, and any product that is similar to or only colorably different from those products, and from infringing, contributorily infringing, or inducing others to infringe the '438 patent, before the expiration of the '438 patent and any additional periods of exclusivity;

(4) Damages or other monetary relief, including prejudgment and post-judgment interest, if Sun engages in the commercial manufacture, use, sale, offer to sell, marketing, distribution, or importation of Sun's ANDA Product, or any product or compound that infringes the '438 patent, or in inducement or contribution of the '438 patent, before the expiration of the '438 patent and any additional periods of exclusivity;

(5) A declaration that this is an exceptional case and an award of reasonable attorneys' fees and expenses to Plaintiffs pursuant to 35 U.S.C. §§ 271(e)(4) and 285;

(6) Plaintiffs' reasonable costs of suit incurred in bringing and prosecuting this action; and

(7) Such further and other relief as this Court may deem just and proper.

L. **As Against Teva:**

(1) Judgment that Teva has infringed, literally or by the doctrine of equivalents, the '438 patent by the submission of ANDA No. 208432, and that the commercial manufacture, use, sale, offer for sale, marketing, distribution, or importation of Teva's ANDA Product, in the United States, will constitute infringement, contributory infringement, and actively inducing infringement of the '438 patent;

(2) Judgment, pursuant to 35 U.S.C. §271(e)(4)(A), that the effective date of any FDA approval of Teva's ANDA No. 208432 shall be no earlier than the date of expiration of the '438 patent and any additional periods of exclusivity to which Plaintiffs are or become entitled;

(3) A preliminary and permanent injunction, pursuant to 35 U.S.C. §271(e)(4)(B) and 283 and Rule 65, Fed. R. Civ. P., enjoining Teva, its officers, partners, agents, servants, employees, parents, subsidiaries, divisions, affiliate corporations, other related business

entities and all other persons acting in concert, participation, or privity with it, and their successors and assigns, from making, using, selling, offering to sell, marketing, distributing, or importing into the United States Teva's ANDA Product and the active ingredient described in Teva's ANDA No. 208432, and any product that is similar to or only colorably different from those products, and from infringing, contributorily infringing, or inducing others to infringe the '438 patent, before the expiration of the '438 patent and any additional periods of exclusivity;

(4) Damages or other monetary relief, including prejudgment and post-judgment interest, if Teva engages in the commercial manufacture, use, sale, offer to sell, marketing, distribution, or importation of Teva's ANDA Product, or any product or compound that infringes the '438 patent, or in inducement or contribution of the '438 patent, before the expiration of the '438 patent and any additional periods of exclusivity;

(5) A declaration that this is an exceptional case and an award of reasonable attorneys' fees and expenses to Plaintiffs pursuant to 35 U.S.C. §§ 271(e)(4) and 285;

(6) Plaintiffs' reasonable costs of suit incurred in bringing and prosecuting this action; and

(7) Such further and other relief as this Court may deem just and proper.

M. **As Against Hikma/West-Ward:**

(1) Judgment that Hikma/West-Ward has infringed, literally or by the doctrine of equivalents, the '438 patent by the submission of ANDA No. 208339, and that the commercial manufacture, use, sale, offer for sale, marketing, distribution, or importation of Hikma/West-Ward's ANDA Product, in the United States, will constitute infringement, contributory infringement, and actively inducing infringement of the '438 patent;

(2) Judgment, pursuant to 35 U.S.C. §271(e)(4)(A), that the effective date of any FDA approval of Hikma/West-Ward's ANDA No. 208339 shall be no earlier than the date of expiration of the '438 patent and any additional periods of exclusivity to which Plaintiffs are or become entitled;

(3) A preliminary and permanent injunction, pursuant to 35 U.S.C. §271(e)(4)(B) and 283 and Rule 65, Fed. R. Civ. P., enjoining Hikma/West-Ward, its officers, partners, agents, servants, employees, parents, subsidiaries, divisions, affiliate corporations, other related business entities and all other persons acting in concert, participation, or privity with it, and their successors and assigns, from making, using, selling, offering to sell, marketing, distributing, or importing into the United States Hikma/West-Ward's ANDA Product and the active ingredient described in Hikma/West-Ward's ANDA No. 208339, and any product that is similar to or only colorably different from those products, and from infringing, contributorily infringing, or inducing others to infringe the '438 patent, before the expiration of the '438 patent and any additional periods of exclusivity;

(4) Damages or other monetary relief, including prejudgment and post-judgment interest, if Hikma/West-Ward engages in the commercial manufacture, use, sale, offer to sell, marketing, distribution, or importation of Hikma/West-Ward's ANDA Product, or any product or compound that infringes the '438 patent, or in inducement or contribution of the '438 patent, before the expiration of the '438 patent and any additional periods of exclusivity;

(5) A declaration that this is an exceptional case and an award of reasonable attorneys' fees and expenses to Plaintiffs pursuant to 35 U.S.C. §§ 271(e)(4) and 285;

(6) Plaintiffs' reasonable costs of suit incurred in bringing and prosecuting this action; and

(7) Such further and other relief as this Court may deem just and proper.

N. **As Against Wockhardt:**

(1) Judgment that Wockhardt has infringed, literally or by the doctrine of equivalents, the ’438 patent by the submission of ANDA No. 208380, and that the commercial manufacture, use, sale, offer for sale, marketing, distribution, or importation of Wockhardt’s ANDA Product, in the United States, will constitute infringement, contributory infringement, and actively inducing infringement of the ’438 patent;

(2) Judgment, pursuant to 35 U.S.C. §271(e)(4)(A), that the effective date of any FDA approval of Wockhardt’s ANDA No. 208380 shall be no earlier than the date of expiration of the ’438 patent and any additional periods of exclusivity to which Plaintiffs are or become entitled;

(3) A preliminary and permanent injunction, pursuant to 35 U.S.C. §271(e)(4)(B) and 283 and Rule 65, Fed. R. Civ. P., enjoining Wockhardt, its officers, partners, agents, servants, employees, parents, subsidiaries, divisions, affiliate corporations, other related business entities and all other persons acting in concert, participation, or privity with it, and their successors and assigns, from making, using, selling, offering to sell, marketing, distributing, or importing into the United States Wockhardt’s ANDA Product and the active ingredient described in Wockhardt’s ANDA No. 208380, and any product that is similar to or only colorably different from those products, and from infringing, contributorily infringing, or inducing others to infringe the ’438 patent, before the expiration of the ’438 patent and any additional periods of exclusivity;

(4) Damages or other monetary relief, including prejudgment and post-judgment interest, if Wockhardt engages in the commercial manufacture, use, sale, offer to sell, marketing, distribution, or importation of Wockhardt’s ANDA Product, or any product or

compound that infringes the ’438 patent, or in inducement or contribution of the ’438 patent, before the expiration of the ’438 patent and any additional periods of exclusivity;

(5) A declaration that this is an exceptional case and an award of reasonable attorneys’ fees and expenses to Plaintiffs pursuant to 35 U.S.C. §§ 271(e)(4) and 285;

(6) Plaintiffs’ reasonable costs of suit incurred in bringing and prosecuting this action; and

(7) Such further and other relief as this Court may deem just and proper.

O. **As Against Hetero:**

(1) Judgment that Hetero has infringed, literally or by the doctrine of equivalents, the ’438 patent by the submission of ANDA No. 208349, and that the commercial manufacture, use, sale, offer for sale, marketing, distribution, or importation of Hetero’s ANDA Product, in the United States, will constitute infringement, contributory infringement, and actively inducing infringement of the ’438 patent;

(2) Judgment, pursuant to 35 U.S.C. §271(e)(4)(A), that the effective date of any FDA approval of Hetero’s ANDA No. 208349 shall be no earlier than the date of expiration of the ’438 patent and any additional periods of exclusivity to which Plaintiffs are or become entitled;

(3) A preliminary and permanent injunction, pursuant to 35 U.S.C. §§ 271(e)(4)(B) and 283, as well as Rule 65 of the Federal Rules of Civil Procedure, enjoining Hetero, its officers, partners, agents, servants, employees, parents, subsidiaries, divisions, affiliate corporations, other related business entities and all other persons acting in concert, participation, or privity with it, and their successors and assigns, from making, using, selling, offering to sell, marketing, distributing, or importing into the United States Hetero’s ANDA

Product and the active ingredient described in Hetero's ANDA No. 208349, and any product that is similar to or only colorably different from those products, and from infringing, contributorily infringing, or inducing others to infringe the '438 patent, before the expiration of the '438 patent and any additional periods of exclusivity;

(4) Damages or other monetary relief, including prejudgment and post-judgment interest, if Hetero engages in the commercial manufacture, use, sale, offer to sell, marketing, distribution, or importation of Hetero's ANDA Product, or any product or compound that infringes the '438 patent, or in inducement or contribution of the '438 patent, before the expiration of the '438 patent and any additional periods of exclusivity;

(5) A declaration that this is an exceptional case and an award of reasonable attorneys' fees and expenses to Plaintiffs pursuant to 35 U.S.C. §§ 271(e)(4) and 285;

(6) Plaintiffs' reasonable costs of suit incurred in bringing and prosecuting this action; and

(7) Such further and other relief as this Court may deem just and proper.

Dated: September 28, 2015

Respectfully submitted,

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